IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE AT NASHVILLE

IN RE: AREDIA® AND ZOMETA® PRODUCTS LIABILITY LITIGATION (MDL No. 1760)	)	**No. 3:06-MD-1760**
	)	**JUDGE CAMPBELL**
	)	**MAGISTRATE JUDGE BROWN**
This Document Relates To: Case No.: 3:05-CV-00718	)	

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR CERTIFICATION OF A DENTAL MONITORING CLASS

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INTRODUCTION

This Court should deny plaintiffs' motion for certification of a "dental monitoring" class pursuant to Federal Rule of Civil Procedure 23, just as the Sixth Circuit and nearly every other federal court have repeatedly denied motions to certify similar monitoring classes. *See, e.g., Ball v. Union Carbide Corp.*, 385 F.3d 713 (6th Cir. 2004); *In re Am. Med. Sys., Inc.*, 75 F.3d 1069 (6th Cir. 1996).[1]

First, plaintiffs' proposed class is inadequately defined, such that class membership itself must be resolved with mini-trials and screening mechanisms. Even the most basic of the class membership criteria – use of Aredia® or Zometa® – will be subject to dispute, protracted discovery, and complicated proofs. Illustrating this point is plaintiffs' own putative class representative Carrie Lee ("Lee"), who did not use either drug, but instead used a generic bioequivalent of Aredia®. Because of the proposed definition's imprecision, this Court need not conduct a full Rule 23 analysis and should simply deny certification at the outset.

Second, plaintiffs cannot meet the commonality, typicality, or adequacy elements of Rule 23(a) because each putative class member used one or both drugs at issue (if at all) during different periods with different labeling or warnings in place; the causation inquiry turns on each individual's medical history; and each class member's claims are governed by a different jurisdiction's laws. The putative representatives again illustrate the point: assuming plaintiffs' expert's theory of causation is correct, neither Lee nor Sybila Duncan ("Duncan") is at an

[1] *See also In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555 (E.D. Ark. 2005); *Zehel-Miller v. AstraZenaca Pharm., LP*, 223 F.R.D. 659 (M.D. Fla. 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003); *Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262 (S.D. Fla. 2003); *In re Baycol Prods. Litig.*, 218 F.R.D.197 (D. Minn. 2003); *In re Paxil Litig.*, 212 F.R.D. 539 (C.D. Cal. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133 (E.D. La. 2002); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520 (N.D. Ill. 1998); *In re Prempro Prods. Liab. Litig.*, No. 4:06-CV-00476, 2007 WL 951878 (E.D. Ark. Mar. 28, 2007) (Ex. 1). All exhibits are attached to the Declaration of Katharine R. Latimer, filed contemporaneously.

increased risk of developing osteonecrosis of the jaw ("ONJ") (and thus they cannot be entitled to monitoring under any formulation of law) because their limited dosing fails to meet the alleged causation threshold established by their own expert.

Plaintiffs implausibly assert that because each putative class member seeks the same relief (dental monitoring), their underlying claims are "common" or "typical" as required by Rule 23(a)(2) and (a)(3). *See* Memorandum of Law in Support of Plaintiffs' Motion for Certification of a Dental Monitoring Class at 34-35 ("Memorandum") (Docket #580). Such superficial analysis is insufficient – if it were not, every proposed class would satisfy Rule 23(a). *See In re Prempro*, 230 F.R.D. at 567 (plaintiffs' attempt to frame class issues broadly to compensate for variation in claims and applicable laws does not eliminate the underlying individual issues preventing certification).

Third, Rule 23(b)(3)'s predominance requirement does not permit certification of any of the classes plaintiffs seek. A class cannot be maintained on behalf of thousands of people exposed to different amounts of different products over different periods during which each had different risk factors for developing ONJ, knew different information regarding the alleged risks of Aredia® and Zometa® use, and where the foregoing difficulties are compounded by critical differences in the substantive law of multiple jurisdictions. *See Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 624-25 (1997); *In re Am. Med. Sys.*, 75 F.3d at 1085; *Perez*, 218 F.R.D. at 266; *Dhamer*, 183 F.R.D. at 530, 532-34.

Fourth, plaintiffs' proposed class is neither the "superior" method of resolving the putative class claims required by Rule 23(b)(3), nor is there any hope of manageability in dealing with the numerous individual issues by aggregate resolution. Mere assurances by "counsel that any problems . . . can be overcome" are insufficient to support certification under Rule 23(b)(3).

Castano v. Am. Tobacco Co., 84 F.3d 734, 742 (5th Cir. 1996); *Weathers v. Peters Realty Corp.*, 499 F.2d 1197, 1200 (6th Cir. 1974).

Finally, plaintiffs' dental monitoring plan is not predicated on any specific risk of injury, but contemplates instead preventing even the alleged risk from occurring. Plaintiffs are asking this Court to "allow these high-risk individuals to obtain free medical tests that the medical community would normally recommend for them in the absence of exposure" in an effort to "convert this class action into free health care." *Perez*, 218 F.R.D. at 273, 275. Among other problems, this suggestion ignores that "medical monitoring and preventative care [have] to be custom-tailored to each individual in order to account for . . . vast differences in usage and risk of injury." *Id.* at 275.

Plaintiffs' proposed medical monitoring class cannot be certified under Sixth Circuit and other applicable precedent. Compelling guidance is found in *In re American Medical Systems*, where the plaintiffs sought medical monitoring of a nationwide class of users of various medical devices manufactured by the defendant. 75 F.3d at 1077. After the district court certified the class, the Sixth Circuit accepted mandamus and reversed, finding that when no "one set of operative facts establishes liability, no single proximate cause applies to each potential class member . . . and individual issues outnumber common issues," the requirements of Rule 23(a) and (b)(3) are not satisfied. *Id.* at 1084.

The Sixth Circuit cautions that "[s]trict adherence to Rule 23 in products liability cases involving drug or medical products which require FDA approval is *especially* important." *Id.* at 1089 (emphasis in original). Yet plaintiffs gloss over Rule 23 in their Memorandum, opting instead to preview their spin on merits issues that they acknowledge cannot be decided at this

stage of the litigation. Docket #580 at 31-32; *see Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974). Plaintiffs' approach should not be countenanced, and their motion should be denied.

I. BACKGROUND

A. Aredia® and Zometa®

Bone is comprised of living tissue and changes throughout life. *See* Expert Report of Professor Graham Russell at 4-12 (describing function and attributes of bone) ("Russell Rep.") (Docket #616). Each year, 2-10% of the adult skeleton is remodeled, with certain cells targeting removal of old bone and other cells following behind to build new bone in its place. *See* Russell Rep. at 5; Expert Report of Robert E. Coleman at 8-9 ("Coleman Rep.") (Docket #617).

Bone metastases, which can occur anywhere in the skeleton, influence the remodeling cycle by increasing bone destruction to a rate that rebuilding mechanisms cannot match. Russell Rep. at 9-12. Individuals with bone metastases are heterogeneous – more aggressive forms of metastases destroy bone more quickly and cause more significant complications. *See* Deposition of Robert E. Coleman at 156:8-157:6 (two breast cancer patients with "[w]hat looks like the same pattern of disease" experience different disease progression, so "no two patients are the same") ("Coleman Dep.") (Ex. 2). Metastases cause fractures, hypercalcemia, severe bone pain, spinal cord compression, and neurologic injury. *See* Russell Rep. at 12; Coleman Rep. at 9; Berenson, James R. and Allan Lipton, *Pharmacology and Clinical Efficacy of Bisphosphonates*, Curr. Opin. Oncol. (1998) 10:566, at 569 ("Berenson/Lipton Article") (Ex. 3).

Aredia® (pamidronate disodium) and Zometa® (zoledronic acid) are in a category of drugs known as bisphosphonates that are designed to prevent bone destruction. Each drug plays a vital role in limiting or preventing the harmful effects of disease-induced bone loss, including debilitating skeletal related events such as bone fractures or spinal cord compression. Coleman Rep. at 9; Russell Rep. at 11-12.

First approved by FDA in 1991, Aredia® is administered intravenously in doses of 60-90 mg for hypercalcemia of malignancy (taken once); 90 mg for multiple myeloma and metastases to bone of breast cancer (taken once monthly and every three to four weeks respectively); and 30 mg for Paget's disease[2] (taken three consecutive days, with possible retreatment). Aredia® label at 22-23 (Ex. 4). Generic bioequivalents of Aredia® became available in 2001 [redacted]. [redacted]

First approved by FDA in 2001, Zometa® is indicated to treat hypercalcemia of malignancy, multiple myeloma, and bone metastases of solid tumors (including breast cancer, prostate cancer and other solid tumors). Zometa® is administered intravenously in doses of 4 mg for all indications (taken once for hypercalcemia of malignancy and every three to four weeks for other indications). *See* Zometa® label at 1 (Ex. 5).[3]

Because of their extraordinary benefits, both drugs are the standard of care treatments for their indications. *See* Coleman Rep. at 9-10, 14-17; Russell Rep. at 13; Report of Allan Lipton at 5-7 ("Lipton Rep.") (Docket #621); *see also* Coleman, Robert E., *The Role of Bisphosphonates in Breast Cancer*. Breast (2004) 13:19, at S19 ("Coleman Article") ("pamidronate and zoledronic acid have demonstrated the greatest clinical benefit based on conservative endpoints" and "zoledronic acid has rapidly become the new international standard of care for patients with bone metastases") (Ex. 6).[4]

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[2] Paget's disease is a non-malignant disorder involving increased abnormal bone formation that can lead to pain, deformity and fracture of affected bones. Russell Rep. at 12.

[3] Zometa® is the only bisphosphonate approved to treat skeletal complications in prostate cancer patients with metastatic bone disease. *See* Report of Walter Stadler at 1 ("Stadler Rep.") (Docket #618).

[4] Aredia® revolutionized the treatment of patients with hypercalcemia of malignancy. What was formerly a difficult to treat and often fatal illness for cancer patients became treatable; physicians "seldom see a patient in the hospital nowadays with hypercalcemia." Deposition of Allan Lipton at 215:17-216:13 ("Lipton Dep.") (Ex. 7). Likewise, without Aredia® or Zometa®, "the vast majority (nearly 70%) of patients with bone metastases . . . will experience one or more . . . skeletal complications during the course of their disease." Coleman Article at S19. The benefits of treatment include a reduced incidence of skeletal-related complications, a delay in time to the first skeletal related

ONJ was observed in the general population, and in individuals with destructive bone diseases in particular, years prior to the availability of either Aredia® or Zometa®. Lipton Dep. at 35:5-36:14 (aware of reports of ONJ in cancer patients receiving chemotherapy, radiation, and corticosteroid treatments in 1970s or 1980s); *infra* at 35-38 (discussing reported risk factors for ONJ). The first case report describing ONJ in an Aredia® or Zometa® user was published in 2003, twelve years after Aredia®'s introduction. *See* Plaintiffs' Compendium of Articles, Vol. 1, at Tab 5. Although similar publications have followed, there is no reliable scientific evidence that either Aredia® or Zometa® cause ONJ, nor has a biological mechanism been established. *See, e.g.*, Russell Rep. at 18, 32-34 (no reliable scientific evidence of causation; postulated mechanisms of action are merely hypothetical); Van den Wyngaert, T. et al., *Osteonecrosis of the Jaw Related to the Use of Bisphosphonates.* Curr. Opin. Oncol. (2007) 19:315, at 316 ("As an emerging disease, the epidemiology of ONJ is in full evolution and hitherto many unknowns exist, as the true causality between the use of bisphosphonates and ONJ remains unproven . . .") ("Van den Wyngaert Art.") (Ex. 9). Even so, Novartis Pharmaceuticals Corporation ("NPC") has amended the warnings on the labeling for each product at various times to address ONJ specifically. *See, e.g.*, Expert Report of Janet Arrowsmith-Lowe at 3 ("Arrowsmith-Lowe Rep.") (Docket #622). NPC also distributed additional information to medical and dental professionals at various times. *See* "Dear Doctor" letters dated Sept. 24, 2004 and May 5, 2005 (informing healthcare providers of changes in Aredia® and Zometa® prescribing information) (Ex. 10); *see also* Coleman Rep. at 18.

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event, and decreased bone pain. *Id.* at S22; Coleman Dep. at 126:10-127:9 (Zometa® benefits include reducing risk of a skeletal related event in half); Berenson/Lipton Article at 599 (individuals with breast cancer experienced "significantly less increase in bone pain, less increase in the use of narcotics, and slower deterioration of performance status in the pamidronate patients than in the placebo group"). Thus, Aredia® and Zometa® significantly enhance the user's quality of life. *See, e.g.,* Transcript of Proceedings from FDA's 2005 Oncologic Drugs Advisory Committee Meeting, Volume II at 240-44, 252-53 (Ex. 8).

B. Plaintiffs

In their Memorandum, plaintiffs argue for a class consisting of former, current, and presumably future Aredia® and/or Zometa® users who claim they are entitled to dental monitoring because NPC is strictly liable or negligent. *See* Docket #580 at 10, 34, 39; Docket #506 at 5-7, 8-9, 13.[5] The stated objective of the monitoring is to prevent a tort from occurring: plaintiffs want NPC to pay to "monitor the dental health" of the class members in order for the members "to avoid the need for invasive dental procedures" – procedures that have nothing to do with the members' use of Aredia® or Zometa® – on the theory that the invasive dental procedures themselves can "trigger" ONJ in Aredia® and Zometa® users. Docket #580 at 4. The Complaint identifies Duncan from California and Lee from Georgia as putative representatives.[6]

In February 1998, doctors diagnosed Duncan with breast cancer, which metastasized to her bones in 2006. *See* Duncan_S-0879-0037-40, Duncan_S-0879-0015 (Ex. 11).[7] Duncan's oncologist, Dr. James R. Waisman, prescribed monthly Zometa® treatments to prevent bone fractures and pain, and possibly improve survival.[8] Duncan received a 4 mg dose of Zometa® on December 11, 2006. *See* Duncan_S-0879-0045-46. After discussing the alleged risk of developing ONJ with Dr. Waisman, she received a second and final 3.5 mg dose of Zometa® on January 11, 2007. *See* Duncan_S-0879-0041. Against Dr. Waisman's advice, Duncan has discontinued her Zometa® treatments. *See* Duncan_S-0879-0107.

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[5]The definition in the operative Fifth Amended Complaint ("Complaint") (Docket #506) is more narrow, referencing only former users of Aredia® and Zometa®.

[6] Plaintiffs have withdrawn Dora Jackson as a third putative representative.

[7] All cited medical records for Sybila Duncan are collected in Exhibit 11. All cited medical records for Carrie Lee are collected in Exhibit 12.

[8] *See* Duncan_S-0879-0015 (recommending that Duncan receive Zometa® infusion monthly because of bone metastases); Duncan_S-0879-0013 (Duncan told about "benefits of Zometa and the fact that it may improve survival"); *see also* Deposition of Dr. James Waisman, at 89:17-23 ("Waisman Dep.") (Ex. 13).

In October 2003, doctors diagnosed Lee with Paget's disease in her skull. Lee_C-1006-0028 (Ex. 12). Lee's endocrinologist, Dr. James Stoever, prescribed four pamidronate infusions between November 2004 and December 2006 to treat her bone pain caused by Paget's disease. *See* Deposition of Dr. James Stoever at 7:3-23, 90:7-19 ("Stoever Dep.") (Ex. 14). Lee received only generic bioequivalents to Aredia®. *See* NPC's Memorandum in Support of Motion for Summary Judgment on Carrie Lee's Claims ("Lee MSJ") (Docket ##628-630). Even after learning of the alleged risk of ONJ, Lee continued to receive pamidronate because of the pain relief it provided. *See* Deposition of Carrie Lee at 150:3-11, 153:9-14 ("Lee Dep.") (Ex. 15).

II. PLAINTIFFS' PUTATIVE CLASS DEFINITION IS SO FACT-DEPENDENT AND TEMPORALLY BROAD THAT THE COURT SHOULD DENY CERTIFICATION WITHOUT RULE 23 ANALYSIS.

Plaintiffs define their proposed class as:

> All persons who reside in jurisdictions that do not preclude certification of a class for dental monitoring or surveillance, who are taking or took Aredia, Zometa, or both who do not have a prior diagnosis of osteonecrosis of the jaw as defined by the American Association of Oral and Maxillofacial Surgeons, which is exposure of the bone in the maxilla or mandible persisting for more than eight weeks, and who have had no radiation therapy to the jaws.

Docket #580 at 10.[9]

Merely assessing eligibility for class membership under plaintiffs' definition would require plaintiff-by-plaintiff mini-trials, a fact that should end this Court's class certification inquiry without the need to conduct any analysis under Rule 23. *See Edwards v. McCormick*, 196 F.R.D. 487, 493 (S.D. Ohio 2000) ("Where named plaintiffs fail to define the class

[9] Plaintiffs contend that the following jurisdictions meet this criteria: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Guam, Hawaii, Idaho, Iowa, Illinois, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and Wyoming.

adequately, the court need not proceed to a full Rule 23 analysis.").[10] Even plaintiffs' "class plan" expert Paul Mulholland admits that the proffered definition contains several subjective criteria for inclusion that can only be resolved after individual discovery (including medical records collection) and adjudication by the Court. Deposition of Paul Mulholland at 297:20-313:14 ("Mulholland Dep.") (Ex. 16). For example:

Product Identification: The Court must determine whether each potential class member who alleges Aredia® use in fact received Aredia® rather than one of many generic versions. *See* Arrowsmith-Lowe Rep. at 3[redacted]. NPC has no liability for alleged injuries to users of generic pamidronate. *See* Lee MSJ at 8 (Docket #630).

Generics, which have separate regulatory histories from Aredia®, have increasingly gained in market share since their 2001 introduction. In fact, it is unlikely that an alleged post-2001 pamidronate user received Aredia®. [redacted]

Determining whether a plaintiff received a generic drug requires implementation of a protracted screening process, including collecting medical records, speaking with treating physicians, and interviewing infusion center personnel. For example, after extensive investigation (which will be required in each case where, as here, neither the plaintiff nor the prescribing physician can definitively identify what pamidronate product plaintiff received), NPC found that putative class representative Lee received four generic pamidronate doses and no Aredia®. *See* Lee_C-1152-

[10] *See also Perez*, 218 F.R.D. at 266 (certification is inappropriate where class definition is not "sufficiently precise and determinable to identify" class members); *In re Paxil*, 212 F.R.D. at 545-46 (same); *Ball v. Union Carbide Corp*., 212 F.R.D. 380, 391-92 (W.D. Tenn. 2002), *aff'd* 385 F.3d 713 (6th Cir. 2004) (same); *Gevedon v. Purdue Pharma*, 212 F.R.D. 333, 337 (W.D. Ky. 2002) (class definition is too imprecise where individualized medical determinations are required to identify members); *White v. Williams*, 208 F.R.D. 123, 129-30 (D.N.J. 2002) (refusing to adopt definition that would "require the Court to conduct a number of mini-trials or to employ some other screening mechanism prior to defining the class"); *Mueller v. CBS, Inc.*, 200 F.R.D. 227, 233 (W.D. Pa. 2001) (same); *Kline v. Sec. Guards, Inc.*, 196 F.R.D. 261, 266-68 (E.D. Pa. 2000) (same); *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 446 (E.D. Pa. 2000) (same).

0048-49 (November 2004 dose) (Ex. 12); Declaration of Kenneth Jozefczyk, M.S., R.Ph. at ¶¶8-9 (during the relevant time period in 2004, infusion center purchased "generic forms" of pamidronate and "did not purchase Aredia, a non-generic bisphosphonate drug manufactured by Novartis.") ("Jozefczyk Dec.") (Docket #626); Stoever Dep. at 60:21-61:3, 90:7-16 (February and September 2005, and December 2006 doses); Declaration of Ray R. Maddox, Pharm.D. at ¶¶8-9 (during those periods, infusion center did not formulate 90 mg Aredia® doses, instead exclusively using generic pamidronate for 90 mg doses) ("Maddox Dec.") (Docket #627).

Even a notation that a plaintiff's physician ordered "Aredia" is insufficient to show that the plaintiff actually received Aredia®.[11] For example, former putative representative Jackson received at least 17 doses of generic pamidronate even though each corresponding physician's order stated "Aredia." *See* Deposition of Jeffrey Harris at 62:19-66:8 (Ex. 17).[12]

Absence of Diagnosis/Absence of Exposed Bone: The Court also must permit "class membership" discovery on and individually resolve whether a plaintiff has been (or should have been) previously diagnosed with ONJ, which plaintiffs define as exposed bone for more than eight weeks. Docket #580 at 10. As numerous professional bodies and even plaintiffs' expert recognize, there is no consensus definition of ONJ. *See* Deposition of David Stanton at 67:8-

[11] *See* Lipton Rep. at 6 (physicians often write "Aredia" as shorthand for pamidronate; whether patient receives brand name or generic pamidronate is determined by infusion center or hospital formulary); Stoever Dep. at 10:11-18, 107:2-6 (writes "pamidronate" on orders based on "training and habits"; never written prescription for "Aredia"); *id.* at 118:23-119:11 (not aware of whether generic versions of pamidronate are on market).

[12] State laws and health care programs affect how pharmacists fill prescriptions. For example, California and Georgia give pharmacists discretion to substitute a generic version of a drug for the prescribed brand name drug unless the prescriber states otherwise. *See* Cal Bus. & Prof. Code § 4073(a) (West 2007); Ga. Code. Ann. § 26-4-81(a) (2007). Georgia Medicaid and Medicare recipients, such as Lee, receive generic drugs when available, unless the prescriber specifically states otherwise. *See* "Pharmacy Program Characteristics," Nat'l Pharm. Council, Pharm. Benefits Under State Medical Assistance Programs 2005-2006, Section 4, p. 4-58, *available at* http://www.npcnow.org/resources/PDFs/medicaid2005/05-06Section4.pdf (listing Georgia as state whose Medicaid program requires dispensing of generic multi-source drugs whenever available) (Ex. 18). In contrast, California law does not mandate that Medicaid recipients receive generic drugs. *Id.* Therefore, even if a physician prescribed "Aredia®," whether a plaintiff actually received Aredia® or a generic may depend on such factors as the discretion of the pharmacist, available stock, whether the plaintiff is a Medicaid recipient, and state law.

68:1, 285:11-22 ("Stanton Dep.") (Ex. 19); Deposition of R.G.G. Russell at 135:6-13 (ONJ "has had a number of definitions" which "probably [have] some overlap with other clinical conditions") ("Russell Dep.") (Ex. 20); Ruggiero, S., Gralow, J., Marx, R., et al., *Practical Guidelines for the Prevention, Diagnosis, and Treatment of Osteonecrosis of the Jaw in Patients With Cancer*. J. Oncology Practice 2:7-14, at 8 (2006) ("there is as yet no consensus definition for ONJ") (Ex. 21).[13] This Court should not accept plaintiffs' invitation to settle definitional disputes about a medical condition in any event; "'the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science, it does not lead it.'" *In re Propulsid*, 208 F.R.D. at 147 (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)).

Thus, a simple diagnosis of ONJ in an individual would not satisfy the membership exclusion; the Court would need to determine whether the diagnosing doctor used the diagnostic criteria adopted for purposes of this case. Some putative class members will have had ONJ but will not have been "diagnosed with" it as required by the class definition; others will meet the general definition but will not in fact have ONJ.[14] In such situations, the Court will have to determine membership status.

Radiation Treatment: Determining whether someone received radiation to the jaw also requires discovery and individual adjudication. Reviewing medical records for specific mention of radiation treatment to this area is insufficient; even if the therapy is targeted to another area, radiation may reach the jaw.[15] For example, in 1982, Duncan received radioactive iodine

[13] Plaintiffs' characterization of the AAOMS definition is itself wrong and underscores the difficulties inherent in the task they ask the Court to undertake. AAOMS defines ONJ to include not merely exposed bone, but exposed *necrotic* bone. Deposition of Robert E. Marx at 188:24-189:17 ("Marx Dep.") (Ex. 22).

[14] One of the former *Anderson* putative class representatives experienced exposed bone for more than eight weeks, well before his alleged Aredia® use, but was not diagnosed with ONJ. *See* Letter Dated Nov. 12, 2001 Regarding F. Fragomeli (produced as exhibit to deposition of Dr. D. Miller) (Ex. 23).

[15] Whether and how much radiation reached the jaw of the putative class member is likely to be contested. *Compare* Ingram_R-0166-0157 ("Repeated . . . CT scan of jaw which demonstrates a pathologic fracture of right mandible.

treatment for her thyroid cancer, Waisman Dep. at 51:17-25, that could result in a variety of oral complications that may damage bone. *See* Report of David Stanton Rep. at 17 ("Stanton Rep.") (Docket #620).

Plaintiffs' class definition – persons who "are taking or took" either drug – also fails to define adequately the "relevant time" of the class, which is the "period during which members of the proposed class incurred the claimed injury." *Manual for Complex Litig. (Fourth)* § 21.222 (2004); *see, e.g., In re Ford Motor Co. Ignition Switch Prods Liab. Litig.,* 194 F.R.D. 484, 495 n.10 (D.N.J. 2000) (plaintiffs bear burden of defining class period in class definition). Plaintiffs' failure to specify a time frame places the Court on perpetual stand-by to resolve numerous individual issues about class inclusion because both drugs are still available and approved by FDA as safe and effective, relevant science continues to emerge, and product labeling and literature have changed and may continue to change over time. The proposed class would also subject NPC to endless liability to former, current, and future users, something prohibited by Rule 23 and NPC's due process rights.[16] Class certification must be denied where "[t]he uncertainty as to the temporal breadth of the class period would only make it more difficult to ascertain who are proper members of the proposed class, and to apply the proposed class definitions." *In re Ford Motor Co.,* 194 F.R.D. at 495 n.10; *see also Fisher v. Ciba Specialty Chems. Corp.*, 238 F.R.D. 273, 301 (S.D. Ala. 2006) (class not adequately defined unless

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Suspect the basis for this is radiation induced osteonecrosis based on Mr. Ingram's history of radiation therapy to the cervical spine. . .") *and* Ingram_R-0249-0050 (same) *with* Ingram_R-0123-0020-23 ("mandible would have very little, if any, radiation due only to scatter. . . . [T]here has not been enough radiation to cause problems to his mandible.") (Ex. 24).

[16] *See Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 845 (1999) (Rule 23 does not change substantive rights of parties); *In re Gypsum Antitrust Cases*, 565 F.2d 1123, 1127 (9th Cir. 1977) ("[A] cutoff date is essential and at some point the matter must be terminated.") (quotation omitted); *Bowman v. UBS Fin. Servs., Inc.,* No. C-04-3525, 2007 WL 1456037, at *3 (N.D. Cal. May 17, 2007) (same) (Ex. 25); *cf. Lee v. Macon County Bd. of Educ.,* 681 F. Supp. 730, 739 (N.D. Ala. 1988) (court supervision of class action should not be open-ended; court has a responsibility to bring litigation to a conclusion).

definition identifies "a particular group harmed during a particular time period in a particular manner such that the district court can utilize objective indica to determine who is and is not part of the class"); *Pettrey v. Enter. Title Agency, Inc.,* 241 F.R.D. 268, 284 (N.D. Ohio 2006) (denying class certification where plaintiffs did not include time limitation in class definition).

Because of the inadequate definition, the Court should deny plaintiffs' certification request and need not proceed to a Rule 23 analysis.

III. THE PROPOSED CLASS DOES NOT SATISFY RULE 23(a).

Like the many plaintiffs in pharmaceutical products liability cases who have unsuccessfully sought medical monitoring classes before them, plaintiffs here have failed to meet the certification threshold requirements of Rule 23(a). Specifically, plaintiffs have failed to meet the requirements of Rule 23(a)(2)-(4), frequently referred to as commonality, typicality, and adequacy. These requirements are not perfunctory – if any one is not met, the court need not reach the 23(b) analysis. *See Amchem*, 521 U.S. at 613 (Rule 23(a) contains "threshold requirements"); *Ball*, 385 F.3d at 727 n.11 (same); *In re Am. Med. Sys.*, 75 F.3d at 1079 (Rule 23(a) contains "prerequisites which must *all* be met before a class can be certified") (emphasis in original).[17]

A. The Commonality Requirement in 23(a)(2) Is Not Met Because the Key Issues in Plaintiffs' Claims Are Inherently Individual.

In assessing commonality in the Sixth Circuit, "[w]hat we are looking for is a common issue the resolution of which will advance the litigation." *Sprague v. Gen. Motors Corp.*, 133 F.3d 388, 397 (6th Cir. 1998); *see also id.* at 398 (commonality requirement not satisfied where "each plaintiff's claim depended upon facts and circumstances peculiar to that plaintiff"); *In re*

[17] Although the number of former, current, and future Aredia® and Zometa® users is sufficient to satisfy Rule 23(a)'s threshold numerosity requirement, plaintiffs' class inclusion criteria are so indefinite that potential class members cannot reasonably be identified. *See supra.*

Am. Med. Sys., 75 F.3d at 1080-81 (same). Plaintiffs have not identified and cannot identify such material, common issues.

Plaintiffs broadly contend that "[c]lass homogeny is present" because each class member wishes to pursue the same claim – dental monitoring. Docket #580 at 34. The Sixth Circuit (like other circuits) has repeatedly rejected such over-generalized contentions. *Ball*, 385 F.3d at 727 (medical monitoring claims raised individual issues preventing satisfaction of commonality requirement); *In re Am. Med. Sys.*, 75 F.3d at 1081 (where proof needed to sustain cause of action varies by class member, commonality not satisfied); *Sprague*, 133 F.3d at 398 (same). The focus of the commonality analysis is qualitative, not quantitative; the requirement is not met where, as here, key elements of plaintiffs' claims require individual proofs. *Sprague*, 133 F.3d at 398. As explained in *Sprague*, "at a sufficiently abstract level of generalization, almost any set of claims can be said to display commonality." *Id.* at 397.

The notion that plaintiffs are prosecuting one homogenous monitoring claim is particularly far-fetched. The very predicate of their claim – the alleged need for monitoring due to increased risk of ONJ caused by any former, current or future use of Aredia® or Zometa® – is categorically dismissed by their expert Marx. According to Marx, an individual must receive an average of nine standard 4 mg doses (but no fewer than six doses) of Zometa® or fourteen standard 90 mg doses (but no fewer than nine doses) of Aredia® before an increased risk of ONJ develops. *See* Marx Dep. at 160:10-161:22 (Ex. 22); *see* NPC's Memorandum in Support of Its Motion for Summary Judgment on Certain Plaintiffs' Claims ("Duncan/Lee MSJ") (Docket ##631-633).[18] Commonality is not satisfied where resolving a plaintiff's claim requires

[18] Marx largely bases his opinion on clinical experience, in which he has "not seen a single case of Zometa related osteonecrosis who have not taken at least six doses." Marx Dep. at 229:22-24. NPC does not concede that plaintiffs' experts' opinions are reliable or based on sound scientific principles. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

individual determinations about each plaintiff's exposure. *Ball*, 385 F.3d at 727 (rejecting commonality because each plaintiff's claim is "highly individualized"); *Perez*, 218 F.R.D. at 271-72 (same).

Marx illustrates the problem with plaintiffs' claim of commonality with a three-dose, no-increased-risk Zometa® example:

> [T]he key here is three doses. You could do five million people and there would be an equal between the placebo and their *three doses of Zometa is not toxic to the bone.* This is a foregone conclusion.
> ***
> *[T]hree doses of Zometa would have no difference between a placebo*. Fine, if you limit three doses, I would be comfortable with that for the entire world.

Marx Dep. at 272:24-273:5, 273:15-18 (emphasis added); *see also* Marx Dep. at 234:24-235:4 (finding one case of ONJ in the placebo arm and one in the zoledronic acid arm of a study was "not a surprising finding[,] they were underdosed below the toxic level"); *see also* Marx Dep. at 48:11-14 (at least six months of Zometa® exposure is required to increase risk of ONJ).

As Marx makes clear, any need for special monitoring (and NPC contends there is no need at all), is a highly individualized inquiry, not a "common" class-wide claim. And perhaps not surprisingly, the plaintiff-specific evidence relevant to the proposed class representatives themselves highlights the point: accepting Marx's theories, neither Duncan nor Lee is at any increased risk of developing ONJ based on their respective exposures. Duncan received two doses of Zometa®, one of which was smaller than standard, so she received less than a third of Marx's threshold. *See supra* at 7. Lee received four doses of pamidronate over 26 months, less than half of Marx's threshold. *See infra* at 18.

It is well established that in medical monitoring claims, individual issues including varying dosing histories (as well as unique factors such as the plaintiff's medical condition)

"dominate[] the causation inquiry. Thus, causation does not provide a common question." *Blain v. SmithKline Beecham Corp.*, 240 F.R.D. 179, 185 (E.D. Pa. 2007); *see also Ball*, 385 F.3d at 727 (liability issues, including existence of and exposure to ground contamination, were not common); *In re Am. Med. Sys.*, 75 F.3d at 1081-82 (commonality not satisfied where plaintiffs received product at different times and each plaintiff's substantive claims required different proof regarding causation because of a variety of other risk factors that could cause alleged injury); *infra* at 34-40 (individual issues regarding causation also prevent satisfaction of predominance requirement); *Perez*, 218 F.R.D. 271-72 (same). Because "the potential for future injury can only be decided by looking to the individual medical histories of the class members," certification is inappropriate. *In re Baycol*, 218 F.R.D. at 213.

The remaining items on plaintiffs' list of "common" issues are inconsequential or incorrect. Docket #580 at 34-35. That Aredia® and Zometa® are only available for intravenous infusion is hardly a "common" issue that materially advances the resolution of plaintiffs' claims as required by *Sprague*. 133 F.3d at 397. The same is true of the alleged "asymptomatic" status of the class members; even if true, that fact is inconsistent with the exclusion criterion in the class definition, which is exposed persons who have not been diagnosed with ONJ after 8 weeks of exposed bone. Docket #580 at 34. Plaintiffs' observation that only NPC sells the drugs at issue is correct, but given the availability [redacted] of generic bioequivalents of Aredia®, [redacted] its manufacture is hardly a material common issue.

There is no "finite" common period of exposure as plaintiffs claim – class members used the different drugs for different periods with different labeling or warnings in place. Moreover, there is no aggregate way to determine the cause of an individual's alleged increased risk of ONJ

in a plaintiff population with numerous risk factors for ONJ. *Blain*, 240 F.R.D. at 185 ("whether the drug did cause the individual plaintiff's [injury] is the determinative question").

Finally, plaintiffs assert – with no support because there is none – that the elements of their putative class members' various medical monitoring claims, as well as "virtually all legal issues" and "virtually all evidence" are common. Docket #580 at 34. Federal courts correctly and repeatedly have rejected similar contentions in similar circumstances. *See supra* at 1; *infra* at 25-27. For example, in *Perez*, the court rejected plaintiffs' request to certify a medical monitoring class in four of the same jurisdictions at issue here, finding that variations among laws in just two, much less four, of those jurisdictions would be too great. 218 F.R.D. at 267. Plaintiffs then requested a Florida-only class, alleging that common issues included whether class members were at an increased risk of contracting serious latent disease because of the defendant's medication, whether each plaintiff was significantly exposed to a hazardous substance, and whether the defendant was negligent. *Id.* at 270-71. The court held that none of plaintiffs' issues satisfied commonality, which is a more stringent test where, as here, plaintiffs seek to resolve all issues, including non-common ones, in a single proceeding. *Id.* at 271. For example, the question of a defendant's negligence depended upon the product warning labels, which had changed over time, and so whether a plaintiff received proper warnings from or abided by the labeling were individual issues. *Id.* The court also concluded that proximate causation was "particularly unsuitable for class treatment" because of the need to consider each plaintiff's other risk factors for the alleged injury. *Id.* at 271-72. NPC refers the Court *infra* at 25-29, 33-34 for a discussion of why the significant variations in medical monitoring laws defeat Rule 23(b)(3)'s predominance requirement.

B. The Putative Class Representatives Are Not Typical of the Class Members, Nor Are Their Claims Sufficiently Similar To Satisfy Rule 23(a)(3).

Satisfying typicality requires that class claims be "fairly encompassed by the named plaintiffs' claims" and based on the same course of conduct. *In re Am. Med. Sys.*, 75 F.3d at 1082 (quotations omitted); *Sprague*, 133 F.3d at 399 (interests of class members and putative representatives must be aligned so that "in pursuing his own claims, the named plaintiff will also advance the interests of the class members") (quotation and citation omitted); *see also Isabel v. Velsicol Chem. Corp.*, No. 04-2297, 2006 WL 1745053, at *6-7 (W.D. Tenn. June 20, 2006) (class representatives and members must allege same injuries) (Ex. 26). Each injury alleged on behalf of absent class members must be shared by at least one named plaintiff, and the named plaintiffs and the class must have the same interests. *See In re Am. Med. Sys.*, 75 F.3d at 1082.

Here, based upon the testimony of plaintiffs' expert, neither putative representative is at an increased risk of developing ONJ because of Aredia® or Zometa® use. *See* Duncan/Lee MSJ (Docket #633) (exposure insufficient to place either at increased risk); Lee MSJ (Docket #630) (Lee never used Aredia® or Zometa®). They have no "injury" as defined by the Complaint, and so cannot appropriately advance the interests of the putative class members.

The putative representatives' medical histories reflect other failures in typicality. Breast cancer patients and other patients with solid tumors that have metastasized to bone generally receive Zometa® every 3-4 weeks. *See* Zometa® label at 1 (Ex. 5). Duncan received only two doses of Zometa®, an atypical treatment for a patient with metastatic skeletal disease. Lipton Rep. at 6. Similarly, Lee's dosing history (with generic pamidronate) differs from that of Aredia® users who have metastatic cancer. Rather than the 90 mg monthly dose recommended for cancer patients (who may comprise the bulk of the putative class), Lee received three 90 mg doses and one 60 mg dose for her Paget's disease over 26 months. The putative representatives'

dosing histories also differ from some dosing instructions on Aredia® and Zometa® labeling, making it highly likely that material factual and legal differences exist between the representatives and the putative class members. And of course, neither of the putative representatives was prescribed Aredia® or Zometa® for multiple myeloma, prostate cancer, or other indications (or off-label uses that would be included in the proposed class).

More broadly, as multiple courts have held, no single plaintiff really can be typical of a class in cases involving individualized product liability claims concerning different drugs, different medical histories, different time periods, and different state laws. *E.g., In re Am. Med. Sys.*, 75 F.3d at 1082. An individual whose claim is governed by California law simply is not typical of one whose underlying claim is governed by Vermont law (or by the law of any of the other 32 jurisdictions encompassed in the putative class). One who began using Aredia® in 1991 is not typical of one who began using Zometa® in 2001, and is not typical of one who began using either product after the addition of ONJ-related information to the labeling. *See Sweet v. Pfizer*, 232 F.R.D. 360, 369 (C.D. Cal. 2005) (changes in drug label during class period create "legal differences between those who took the drug before the labeling change and those who took the drug after the addition" and defeat typicality); *Sprague*, 133 F.3d at 399 (typicality lacking when putative class members' claims were dependent upon individualized facts, including representations and communications from defendant). One who discontinued the drug against her doctor's advice is not typical of one who continues to receive it, and one who continues the drug after consultation with her doctor about ONJ is not typical of one whose doctor did not provide ONJ-related information.

Where, as here, differences exist in applicable laws and between the "representatives themselves, and among them and the class members," any general similarities in their claims are

"overwhelm[ed] . . ., defying typicality." *Blain*, 240 F.R.D. at 187; *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 460 (E.D. La. 2006) (individual issues such as causation, the availability of affirmative defenses, and plaintiffs' differing medical histories defeat typicality). For these reasons and those that defeat commonality, *see supra*, and predominance, *see infra*, plaintiffs have failed to satisfy the typicality requirement.

C. Lee and Duncan Are Not Adequate Class Representatives under 23(a)(4).

Representatives must fairly and adequately represent the class. This requirement is not met where, as here, representatives have interests different from the class members and therefore have less incentive to prosecute the class claims vigorously through class counsel. *Amchem*, 521 U.S. at 627 (varying medical histories and other differences between representatives and members of class defeat adequacy); *In re Am. Med. Sys.*, 75 F.3d at 1083 (same); *see also Blain*, 240 F.R.D. at 189 (differences that prevent findings of commonality and typicality also make proposed representatives inadequate); *In re Vioxx Prods.* 239 F.R.D. at 460 (same).

Duncan is not an adequate representative of any class proposed by plaintiffs. Her claim – assuming that she has one – is governed by California law, making her inadequate to represent those bringing claims under the laws of other states. For example, under California law, Duncan must prove through reliable medical expert testimony that the proposed recommended monitoring is reasonable. *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 824 (Cal. 1993). This is not the only criterion, however, for a class member to whom West Virginia law applies. *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424, 432-34 (W. Va. 1999) (allowing consideration of subjective desire for testing).[19]

[19] Putative representatives from one state are inadequate to represent absent class members whose claims would be governed by the law of another state because the representatives lack standing to bring claims under another state's law. *Perez*, 218 F.R.D. at 267-68 (citing *Prado-Steiman v. Bush*, 221 F.3d 1266, 1279-80 (11th Cir. 2000)).

Further, Duncan would not be an adequate representative of a California-only class; her dosing history is atypical and she has ONJ risk factors different from the absent class members. Duncan also is not an adequate representative of users of Aredia® only or users of both Aredia® and Zometa®, who according to Marx, have different risks for developing ONJ than those who use only Zometa®. *See* Marx Dep. at 50:21-52:14.

In all but their 34-jurisdiction proposal, plaintiffs drop their request for Lee to be a class representative. Even if the numerous other individual differences between Lee and the putative class members were not present, she is inadequate because she never used Aredia® or Zometa®. *See* Lee MSJ (Docket #630).

IV. THE PUTATIVE DENTAL MONITORING CLASS FAILS RULE 23(b)(3)'s PREDOMINANCE TEST BECAUSE IT IS RIDDLED WITH INDIVIDUAL ISSUES.

The Court must look behind the claims and defenses of the parties – as well as the evidence needed – in making its predominance assessment under Rule 23(b)(3). *In re Am. Med. Sys.*, 75 F.3d at 1078-79. Here, because individual issues outnumber and outweigh any common ones, the predominance requirement is not satisfied. *See id.* at 1085 (few common issues do not predominate where "the products are different, each plaintiff has a unique complaint, and each receive[d] different information and assurances from his treating physician"). Courts routinely reject multi-jurisdiction medical monitoring classes because medical monitoring claims, as well as the underlying theories of liability on which they depend, implicate irreconcilable variations in state law that must be adjudicated on a plaintiff-by-plaintiff basis. *See supra* n.1; *Spence v. Glock*, 227 F.3d 308, 313 (5th Cir. 2000) (Rule 23 cannot be used to change the law otherwise applicable to a plaintiff's claim). Indeed, where the laws of different jurisdictions would apply to class members' claims, as here, it is "difficult to fathom how common issues could

predominate." *Castano*, 84 F.3d at 743 n.15; *see supra and infra* (class also fails commonality, typicality, adequacy, and manageability requirements on that basis).

Other critical individual issues exist here, such as differing medical histories among the class members, differences in what each class member and his treating physicians knew or should have known about Aredia® and Zometa®, and varying affirmative defenses. Such issues weigh powerfully against a finding of predominance. *See, e.g., Amchem*, 521 U.S. at 624.

A. The Proposed Class Raises Numerous Choice of Law and State Law Issues That Defeat the Predominance Requirement.

The choice of law inquiry "pervades every element" of Rule 23 and must be "tackled at the front end" of every class certification inquiry. *In re Prempro*, 230 F.R.D. at 561. Once addressed, it is "not surprising that all relevant Court of Appeals and the bulk of relevant district court decisions have rejected class certification in products liability cases" involving multiple jurisdictions under Rule 23(b)(3). *In re Rezulin*, 210 F.R.D. at 65-66; *see, e.g.*, *In re Baycol*, 218 F.R.D. at 208 (variations in state law prevent satisfaction of predominance requirement); *In re Vioxx*, 239 F.R.D. at 459 (need to apply law of each plaintiff's home state to his or her claims presents insurmountable "problems for the typicality, adequacy, predominance, and superiority requirements"); *Lewallen v. Medtronic USA, Inc.*, No. 01-20395, 2002 WL 31300899, at *5 (N.D. Cal. Aug. 28, 2002) (common questions do not predominate in nationwide class action seeking medical monitoring because such laws differ, requiring plaintiff-specific choice of law analysis) (Ex. 27).[20]

[20] *See also In re Bridgestone/Firestone Inc. Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1016-18 (7th Cir. 2002) ("No injury, no tort, is an ingredient of every state's law"; reversing class certification due to insurmountable variations in states' laws); *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1192 n.8 (9th Cir.), *as amended* 273 F.3d 1266 (2001) (noting in *dicta* that variations in state laws regarding medical monitoring would prevent subclassing based on whether states recognize medical monitoring as a separate claim or as a remedy).

Plaintiffs claim there are "trivial distinctions" in the law and "minor differences among the statutory schemes" of the 34 jurisdictions they single out as "not prohibit[ing]" medical monitoring. Docket #580 at 36. No support is offered for these assertions because there is none. Instead, claims and defenses exist that "affect[] the individuals in different ways" or "depend upon facts peculiar to each plaintiff's case," and so certification is not appropriate. *In re Am. Med. Sys.*, 75 F.3d at 1084-85 (granting mandamus, in part, because district court failed to consider variations in states' negligence laws).[21] Further, no jury could be expected to understand, separate, and apply the numerous instructions that would be required if plaintiffs' medical monitoring, strict liability, and negligence claims are tried in the aggregate. *In re Am. Med. Sys.*, 75 F.3d at 1085 (rejecting certification where it would be "impossible" to instruct jury on all applicable laws). Rule 23(b)(3)'s predominance requirement prohibits certification under such impossible circumstances.[22]

1. This Court should not predict the law of the 25 of 34 jurisdictions in the putative class that do not recognize medical monitoring.

Twenty-five of the 34 jurisdictions comprising the putative class have not considered whether medical monitoring recovery is available in the absence of current physical injury. *See*

[21] *See also Castano*, 84 F.3d at 741 (choice of law issues presented by putative classes that require application of multiple jurisdictions' laws "swamp any common issues and defeat predominance"); *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 147-49 (3d Cir. 1998) (affirmative defenses such as contributory negligence, consent, assumption of risk, and statute of limitations raise individual issues making certification inappropriate); *Thompson v. Am. Tobacco Co.,* 189 F.R.D. 544, 556 (D. Minn. 1999) (same); *Dhamer*, 183 F.R.D. at 531-32 (individual issues relevant to learned intermediary defense predominated); *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 490-91 (E.D. Pa. 1997) (plaintiff's knowledge of risks as related to assumption of risk/consent to exposure are individual inquiries preventing satisfaction of 23(b)(3)'s predominance requirement); *Harding v. Tambrands Inc.*, 165 F.R.D. 623, 629-30 (D. Kan. 1996) (certification inappropriate where significant common issues of law were lacking due to state law variations); *Lewallen*, 2002 WL 31300899, at *4 (plaintiff-specific issues such as statute of limitations, consent, and assumption of risk prevent certification).

[22] Given the substantial precedent against certification of a multi-jurisdiction dental monitoring class, plaintiffs propose that this Court certify a medical monitoring class of all California plaintiffs. A "California plaintiffs" class would present many other individual issues relating to causation, medical history, timing, warnings, and various defenses that would predominate over any possible common questions and defeat superiority and manageability. *See supra* at 35. Nor is it clear that this MDL Court ought to supervise a California-only class in any event.

Ex. 28 (Chart – Status of Medical Monitoring in Putative Class Jurisdictions). In nine of those 25 jurisdictions, federal courts have attempted to predict whether the state court would allow medical monitoring and have reached divergent conclusions. *Compare Parker v. Brush Wellman, Inc.*, 377 F. Supp. 2d 1290, 1302 (N.D. Ga. 2005), *aff'd in relevant part*, 230 F. App'x 878 (11th Cir. 2007) (Georgia law does not allow for the recovery of medical monitoring expenses if a plaintiff has suffered "subclinical injuries" or no injury), *with Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 n.7 (6th Cir. 2005) (noting that although Tennessee law is "murky," medical monitoring is possible remedy for tort claim rather than cause of action).[23]

Under *Erie*, federal courts may not create state law. *See City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002) ("it is not the role of a federal court to expand state laws in ways not foreshadowed by state precedent"); *see Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 77-78 (1938); *Castano*, 84 F.3d at 750 ("It is far more desirable to allow state courts to apply and develop their own law than to have a federal court" guess); *Little v. Purdue Pharma. L.P.*, 227 F. Supp. 2d 838, 849 (S.D. Ohio 2002) ("given the fact that this presents a case of first impression in the courts of Ohio, a federal court should be wary of divesting the state courts of the first opportunity to rule on the matter"). This is particularly true of a MDL court, whose primary purpose is to coordinate pre-trial matters before remand, not create new law in the home jurisdictions of the cases before it. *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791,

[23] Virtually conceding that the Court should not predict that jurisdictions with unsettled law would recognize medical monitoring in the absence of present injury, plaintiffs alternatively request that this Court refer the question of whether Georgia would do so to the Georgia Supreme Court. Docket #580 at 40 n.12. This request should be denied for several reasons. First, even assuming Georgia recognized such a claim, other individual issues inherent in medical monitoring claims prevent class certification, which is the issue before this Court. *See infra.* Second, a certified question is only appropriate if state law is genuinely uncertain. *Curtis 100, Inc. v. Martin*, 197 F. App'x. 412, 426 (6th Cir. 2006) (refusing to certify question to Georgia Supreme Court where state court had analyzed issue). As discussed in *Parker*, 377 F. Supp. 2d at 1302, Georgia tort law requires an injury; plaintiffs have offered no basis for this Court to conclude that, if asked, the Georgia Supreme Court would change this longstanding principle of state tort law. Finally, certification is inappropriate because the availability of medical monitoring is not

798 (N.D. Ohio 2004) (MDL court's role is to preside over matters common to all cases, not rule on "cumbersome, case-specific legal issues"), *aff'd* 447 F.3d 861 (6th Cir. 2006); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997 WL 109595, at *2 (E.D. Pa. Mar. 7, 1997) ("primary purpose behind the establishment of a multidistrict litigation transferee court was and is to promote efficiency through the coordination of discovery," not to "[put] itself in the shoes of the transferor courts, whose duty would be to put themselves in the shoes of the state courts in which they sit") (Ex. 31).[24]

2. The evidence required to prevail in the eight jurisdictions that recognize medical monitoring varies significantly.

If the Court denies certification of the 34-jurisdiction class, plaintiffs alternatively ask for certification of a 13-jurisdiction class. Docket #580 at 37. Individual state law issues would still overwhelmingly predominate, however, and certification should be denied.

The law regarding medical monitoring is not clear in five of the 13 jurisdictions comprising the alternate class. In Tennessee, Colorado, Guam, and Illinois, state-level courts have not addressed whether medical monitoring is a viable claim or remedy. The federal opinions plaintiffs cite contain no analysis of the jurisdiction's law, entitling those predictions to no weight. *See Zehel-Miller*, 223 F.R.D. at 663 (finding "no justification" to speculate what state courts would conclude). In New Jersey, the most recent Supreme Court authority would prohibit medical monitoring claims by those who "have not suffered an injury or condition resulting from [toxic] exposure." *Theer v. Philip Carey Co.*, 628 A.2d 724, 733 (N.J. 1993) (describing *Ayers*

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an issue uniquely likely to arise in federal court. *See Geib v. Amoco Oil Co.*, 30 F.3d 133, 1994 WL 376900, at *2 (6th Cir. 1994) (table) (Ex.30).

[24] If the Court were inclined to speculate, analysis of state law strongly indicates that medical monitoring claims would not be recognized in many of the jurisdictions whose law is unsettled. *See, e.g.*, *Kelley v. Cowesett Hills Assocs.*, 768 A.2d 425, 430 (R.I. 2001) (possibility of contracting cancer not viable cause of action); *Bernier v. Raymond Indus.,* 516 A.2d 534, 542 (Me. 1986) (mere exposure to asbestos, without present injury, is not actionable

v. Jackson Twp., 525 A.2d 287, 312 (N.J. 1987), as a "special compensatory remedy designed to address unique harm" that "is not easily invoked").[25]

In the remaining eight jurisdictions, there is no uniform law of medical monitoring; as numerous federal courts have found, existing variations defeat predominance. *See, e.g., Zehel-Miller*, 223 F.R.D. at 663 ("fact that medical monitoring is not treated uniformly throughout the United States creates a myriad of individual legal issues" that defeat predominance and superiority); *Dhamer*, 183 F.R.D. at 533 (medical monitoring is not a uniform concept; differences include elements plaintiff must prove to establish claim and whether physical injury must be present); *Arch*, 175 F.R.D. at 489-90 (whether medical monitoring is needed "is highly individualized and militates against Rule 23(b)(3) certification"); *Sanders v. Johnson & Johnson, Inc.*, No. 03-2663, 2006 WL 1541033, at *9 (D.N.J. June 2, 2006) (variations in burdens of proof regarding medical monitoring defeat predominance) (Ex. 32). One federal court already has rejected certification of a class involving only four of the thirteen jurisdictions identified by plaintiffs here. *See Perez*, 218 F.R.D. at 267 (putative class of Colorado, Florida, Illinois, and Pennsylvania residents could not be certified because of variations in state laws and because medical monitoring laws in Illinois and Colorado were unsettled).

Whether a medical monitoring claim is recognized as a separate cause of action (Florida, Pennsylvania, Utah, and West Virginia), as an element of damages (Arizona, California, and Ohio), or both (New York), key differences affect what plaintiffs must show to meet their burden of proof. *See* Ex. 29 (overview of selected differences in medical monitoring). For example:

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harm); *Payton v. Abbott Labs*, 437 N.E.2d 171, 180-81 (Mass. 1982) (recovery for increased risk not allowed absent current physical injury).

[25] The New Jersey Supreme Court is considering a pharmaceutical case that may resolve this conflict. *See Sinclair v. Merck & Co.*, 913 A.2d 832 (N.J. Super. 2007) (noting conflict and that unlike environmental exposure cases such as *Ayers*, product liability actions are governed by a New Jersey products liability act that requires "harm" (defined

- Some jurisdictions require that the prescribed monitoring regime must be different from that normally recommended in the absence of exposure. *See, e.g., Redland Soccer Club, Inc. v. Dep't of the Army*, 696 A.2d 137, 145-46 (Pa. 1997). Other jurisdictions do not have that requirement. *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979-81 (Utah 1993); *see also* Ex. 29 (additional variations).

- Before medical monitoring can be ordered, Florida and Utah require proof that a test exists to make early detection of a disease possible. *See*, *e.g.*, *Petito v. A.H. Robins Co.,* 750 So. 2d 103, 106-07 (Fl. Dist. Ct. App. 1999); *Hansen*, 858 P.2d at 979. West Virginia has a more lenient standard. *Bower*, 522 S.E.2d at 433-34 (requiring only potential existence of monitoring procedures); *see also* Ex. 29 (additional variations).

- Some jurisdictions require that a plaintiff show he is at risk for a latent disease, whereas others require a showing of an increased risk of a serious disease. *Compare Bower*, 522 S.E.2d at 432-33, *with Hansen*, 858 P.2d at 979; *see also* Ex. 29 (additional variations).

- Some jurisdictions require "significant" exposure to a hazardous or toxic substance, while others require only exposure to the substance at greater than background levels. *Compare Bower*, 522 S.E.2d at 432, *with Redland*, 696 A.2d at 145-46; *see also* Ex. 29 (additional variations).

- Some states require proof that a plaintiff is at a significantly increased risk of developing a disease because of the exposure, yet others require a plaintiff to demonstrate a relative increase in risk as compared with that of the general population. *Compare Redland*, 696 A.2d at 145-46, *and Petito*, 750 So. 2d at 106-07, *with Burns v. Jaquays Mining Corp.*, 752 P.2d 28, 31 (Ariz. Ct. App. 1987), *and Potter*, 863 P.2d at 824-25; *see also* Ex. 29 (additional variations).

Plaintiffs' primary "support" for a multi-jurisdiction medical monitoring class is the oft-rejected district court opinion of *In re Telectronics Pacings Sys., Inc.*, 172 F.R.D. 271 (S.D. Ohio 1997). Docket #580 at 37-38. *Telectronics* involved certain recalled pacemakers that, upon malfunction of lead wires, allegedly caused a direct and immediate injury to the heart and nearby blood vessels. 172 F.R.D. at 277. The court found that certification of a multi-jurisdiction medical monitoring class was proper because all recipients required the same monitoring and the defendant was already participating in an FDA-approved program providing recipients with medical screening and reimbursement for medical expenses. *Id.* at 277, 287. According to the

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as personal physical illness, injury, or death) to recover); *appeal pending*, 921 A.2d 446 (N.J.). These and the state court cases cited in this section are included in compendiums filed contemporaneously in paper copy with the Court.

Telectronics court, the only disputed issues were whether the current medical monitoring program was adequate and whether the defendant should continue it. *Id.* at 286-87. Plaintiffs' claim that the *Telectronics* court certified a class of jurisdictions "that share common elements of substantive medical monitoring law" is incorrect – the court found that because the defendant conceded liability and a program was already in place, it need not address variations in medical monitoring laws among jurisdictions not requiring present physical injury. *Id.* at 287.

The factual and legal situation here is very different. NPC has not conceded liability. Moreover, FDA considers Aredia® and Zometa® safe and effective and has not requested that NPC establish a medical monitoring program for users, a factor that alone justifies denying certification under Rule 23(b)(3)'s superiority requirement, discussed *infra*. Causation and the need for and benefits of monitoring are hotly contested in this litigation. In *Telectronics*, the court specifically contrasted the conceded medical device case before it with pharmaceutical product and latent disease cases such as this one, where "the individual causation question tends to be the overarching issue . . . and it overshadows other less complex issues and precludes the common issues from predominating." *Id.* at 289. The *Telectronics* court recognized that its holding was "the exception to the general rule that medical products liability actions require extensive proof of individualized issues." *Id.* at 288.

When faced with facts more similar to those before this Court, numerous federal courts have concluded that *Telectronics* is inapplicable. For example, the Eighth Circuit reversed the only district court that relied on *Telectronics* to certify a class. *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) ("the medical monitoring class presents a myriad of individual issues making class certification improper"); *see also Zinser*, 253 F.3d 1189-90 (distinguishing *Telectronics* and holding that Rule 23 did not permit certification of disputed medical monitoring

class); *Dhamer*, 183 F.R.D. at 533 (same; finding "[m]edical monitoring is not a uniform concept among the states"); *In re Paxil*, 212 F.R.D. at 547 (*Telectronics* was an "exceptional case" as the causation inquiry was "particularly black and white" as opposed to the inquiry in pharmaceutical mass tort actions).[26] Other courts, including some in its own jurisdiction, have simply refused to follow *Telectronics*. *See, e.g., Kemp v. Medtronic*, No. 1:97-CV-00103, 1998 WL 35161989 (S.D. Ohio Feb. 11, 1998) (denying certification of similar class) (Ex. 33). By not analyzing any jurisdiction's law and instead relying on a marginalized district court opinion that contradicts Sixth Circuit and other precedent, plaintiffs have failed to meet their burden of proving that they satisfy the predominance requirement.[27]

3. Differences in the underlying theories of liability prevent certification under Rule 23(b)(3).

In the eight jurisdictions that recognize varying forms of medical monitoring, each putative class member must establish an underlying theory of liability.[28] Therefore, to proceed as a class, plaintiffs must establish that both medical monitoring laws as well as the two underlying legal theories pleaded in the Complaint – strict liability and negligence – are uniform. The Court must conduct a plaintiff-by-plaintiff choice of law analysis, a requirement that defeats predominance. *See In re Am. Med. Sys.*, 75 F.3d at 1085 (class certification is inappropriate

[26] Although the Sixth Circuit never heard an appeal on the merits of the *Telectronics* court's Rule 23(b)(3) medical monitoring decision, subsequent Sixth Circuit rulings indicate that a multi-jurisdiction medical monitoring class cannot be certified. *See Ball,* 385 F.3d at 726-28 (rejecting multi-jurisdiction medical monitoring class because plaintiffs' claims raised individualized issues defeating commonality and typicality); *cf. Sprague*, 133 F.3d at 396-99 (district court erred in certifying class whose claims were based upon individualized facts).

[27] The only other case cited (again without any analysis) by plaintiffs is *In re Diet Drugs Prods. Liab. Litig.*, No. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999) (Ex. 34), which is now viewed as "unpersuasive authority" in light of the Third Circuit's decision in *Barnes v. Am. Tobacco*. *See Paige v. Phila. Hous. Auth.*, No. Civ. A. 99-0497, 2003 WL 22135961, at *4 n.3 (E.D. Pa. Aug. 18, 2003) (Ex. 35); *see also, e.g., Perez*, 218 F.R.D. at 274 (refusing to follow *Diet Drugs*).

[28] *See Petito*, 750 So. 2d at 106 (plaintiff must demonstrate defendant's negligence); *Redland*, 696 A.2d at 145 (same); *Hansen*, 858 P.2d at 979-81 (exposure must be caused by defendant's negligence); *Potter*, 863 P.2d at 823 (requiring showing or entitlement to recovery under traditional tort theory); *Wilson v. Brush Wellman, Inc.*, 817

because instructing the jury on different negligence and other laws applicable to nationwide class would be "impossible"); *Blain*, 240 F.R.D. at 191 (predominance requirement not met where "[d]epending on the individual's home state, defenses may or may not be applicable, or may be applied differently); *Sanders,* 2006 WL 1541033, at *9 (differences among state laws of negligence and strict liability prevent resolution of nationwide class).

a. The elements of strict liability claims and the available affirmative defenses vary by jurisdiction.

Variations in strict liability laws and the need to apply the correct law to each class member's claims defeat predominance. *See Castano*, 84 F.3d at 742 n.15 (variations in strict liability laws magnify differences among putative class members and defeat predominance); *Norwood v. Raytheon Co.,* 237 F.R.D. 581, 597-98 n.37-42, 599-600 (W.D. Tex. 2006) (same); *In re Baycol*, 218 F.R.D. at 208 (same); *see also* Ex. 36 (overview of selected differences in strict liability law in jurisdictions included in plaintiffs' putative classes).

The differences in applicable law are not superficial; instead, they can dramatically affect the outcome of a plaintiff's claim. For example, plaintiffs claim NPC is strictly liable for failing to warn them of the alleged increase in risk of ONJ. Docket #506 at 22-28. However, some jurisdictions in the putative 34- and 13-jurisdiction classes do not recognize strict liability failure-to-warn claims. *See Hahn v. Richter*, 673 A.2d 888 (Pa. 1996) (failure-to-warn claims can only be brought as negligence claims); *Olson v. Prosoco, Inc.,* 522 N.W.2d 284, 289-90 (Iowa 1994) (same).

The elements of and defenses to strict liability claims vary by jurisdiction. For example:

- In some jurisdictions, a rebuttable presumption arises that a product warning is adequate if it is conveyed with a FDA-approved drug. *See, e.g.,* N.J. Stat. Ann. § 2A:58C-4 (West

N.E.2d 59, 61 (Ohio 2004) (same); *Bower*, 522 S.E.2d at 433 (plaintiff must demonstrate tortious conduct of defendant); *Burns*, 752 P.2d at 33 (same).

2007); Tenn. Code Ann. § 29-28-104 (West 2007). In other jurisdictions, no statutory presumption is available. *See also* Ex. 36 (additional variations).

- Jurisdictions apply different tests to determine liability. Some (including Utah) use the "consumer expectation test," which imposes liability if a product fails to perform as safely as an ordinary consumer would expect. *See* Utah Code Ann. §78-15-6 (West 2007). However, Alaska measures the product against the expectations of an "ordinary doctor" while other jurisdictions (such as Ohio) have rejected the consumer expectations test entirely, instead applying a "risk-utility" test, which measures the utility of a product against the potential risk of harm. *See* Ohio Rev. Code Ann. § 2307.75 (West 2007); *Shanks v. Upjohn Co.,* 835 P.2d 1189, 1195 (Alaska 1992); *see also* Ex. 36 (additional variations, including different interpretations of each test).

- In some jurisdictions, plaintiffs asserting design defect claims are required to prove that the product was "unreasonably dangerous." *See, e.g., Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1175 (Colo. 1993). However, in others, the standard is merely "dangerous," *Stewart v. Budget Rent-A-Car Corp.,* 470 P.2d 240, 243 (Haw. 1970), and in some, neither standard is a required element of a plaintiff's case. *Butaud v. Suburban Marine & Sporting Goods, Inc.,* 543 P.2d 209, 213-14 (Alaska 1975); *Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1163 (Cal. 1972); *see also* Ex. 36 (additional variations).

- Statutes of limitation also vary by jurisdiction. *See Thompson*, 189 F.R.D. at 556 (need for individual application of statute of limitations defense is "an insurmountable problem precluding class certification"); *Lewallen*, 2002 WL 31300899, at *5 (same). For example, Tennessee's statute of limitation for product liability claims is one year, Tenn. Code Ann. § 28-3-104(b) (West 2007), while West Virginia's statute of limitation for personal injury claims is two years, W. Va. Code Ann. § 55-2-12 (West 2007), Connecticut's statute of limitation is three years, Conn. Gen. Stat. Ann. §52-577a(a) (West 2007), and Maine's statute of limitation is six years. Me. Rev. Stat. Ann. tit. 14 § 752 (2007); *see also* Ex. 36 (additional variations).

- Jurisdictions have taken different approaches regarding the applicability and/or the interpretation of comment k to § 402A of the Restatement (Second) of Torts, which if adopted, means that in certain circumstances, a manufacturer is not strictly liable for a design defect if a proper warning was provided. Some jurisdictions apply this defense as an exception to strict liability for all prescription pharmaceutical products, but others have rejected comment k entirely or apply it on a case-by-case basis. *Compare Grundberg v. Upjohn Co.,* 813 P.2d 89, 99 (Utah 1991) (adopting comment k) *with Collins v. Eli Lilly & Co.,* 342 N.W.2d 37, 51-52 (Wis. 1984) (rejecting comment k); *Adams v. G.D. Searle & Co.,* 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991) (comment k applied on a case-by-case basis). Yet other jurisdictions, such as Guam, have not addressed whether comment k applies. *See also* Ex. 36 (additional variations).

- The "learned intermediary doctrine" is an important defense in pharmaceutical product liability actions under which a prescription drug manufacturer who provides an adequate warning to a prescribing physician is not required to directly warn the ultimate consumer. Some jurisdictions permit a defendant to raise this defense, while others do not.

Compare McComb v. Synthes (U.S.A.), 587 S.E.2d 594, 594-95 (Ga. 2003) (affirming summary judgment under learned intermediary doctrine) *with State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007) (declining to adopt learned intermediary doctrine in pharmaceutical product liability case based on specific facts); *see also* Ex. 36 (additional variations).

b. Jurisdictions have adopted various interpretations of negligence principles and recognize different affirmative defenses.

Just as with strict liability, variations in negligence standards and defenses predominate over any common issues. *See, e.g., In re Baycol*, 218 F.R.D. at 212 (negligence determinations are "inextricably intertwined with individual issues," therefore common questions do not predominate and certification is inappropriate). Even though in many jurisdictions, negligence claims are based on duty, breach, proximate cause, and damages, the meaning of each element has diverged as each state's common law has evolved. *See In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir.), *cert. denied*, 516 U.S. 867 (1995) (although the elements of a negligence claim at common law sound familiar, "subsidiary concepts such as duty of care, foreseeability, and proximate cause, may . . . differ among the states only in nuance, . . . [b]ut nuance can be important.").[29] For example:

- The differences among the definitions for proximate cause are irreconcilable. Several jurisdictions define proximate cause as "a cause which, in natural and continuous sequence, produces the injury and without which the injury would not have occurred." *Klimple v. Bahl*, 727 N.W.2d 256, 258 (N.D. 2007) (quotation omitted); *Robertson v. Sixpence Inns of Am., Inc.,* 789 P.2d 1040, 1047 (Ariz. 1990); *Nissan Motor Corp. in Guam v. Sea Star Group Inc.*, No. CVA01-001, 2002 WL 1471713, at *8 (Guam Apr. 9, 2002). Some incorporate the concept of foreseeability into proximate cause, but others exclude it. *Compare Walcott v. Total Petroleum, Inc.*, 964 P.2d 609, 611 (Colo. Ct. App. 1998) ("[F]oreseeability is the touchstone of proximate cause"), *with Dodge v. McArthur*, 223 A.2d 453, 454 (Vt. 1966) ("[P]roximate cause relates only to cause-in-fact, with no foreseeability required"). Others have adopted the substantial factor test from the Restatement (First) of Torts, § 431. *See Estate of Joshua T. v. State*, 840 A.2d 768, 771 (N.H. 2003); *see also* Ex. 37 (overview of additional variations).

[29] Where a product liability statute supersedes the common law, plaintiffs must prove entirely different elements. *See, e.g.*, N.J. Stat. Ann. § 2A:58C-1(b)(3) (West 2007); Conn. Gen. Stat. Ann. § 52-572n(a) (West 2005).

- The applicability of comparative or contributory negligence defenses also varies widely by jurisdiction. In some, *any* negligence by the plaintiff bars recovery. *Wingfield v. Peoples Drug Store, Inc.*, 379 A.2d 685, 687 (D.C. 1977); *Harrison v. Montgomery County Bd. of Educ.*, 456 A.2d 894, 905 (Md. 1983). South Dakota law completely bars recovery if a plaintiff's contributing negligence is more than "slight." *Westover v. E. River Elec. Power Coop.*, 488 N.W.2d 892, 897 (S.D. 1992). Others have comparative negligence doctrines that reduce recovery in proportion to the extent of plaintiff's negligence. *See* Fla. Stat. § 768.81(2) (2007); P.R. Laws Ann. tit. 31 § 5141 (2004). Yet other jurisdictions' comparative negligence law bars recovery if a plaintiff's negligence exceeds the defendant's negligence. *See, e.g.*, Vt. Stat. Ann. tit. 12 § 1036 (2007); Idaho Code Ann. § 6-1404 (2007); *id.* § 6-801. Hawaii shifts between these doctrines depending on the cause of action. Haw. Rev. Stat. § 663-31 (2006) (modified comparative negligence applies in negligence cases); *but see Armstrong v. Cione*, 738 P.2d 79, 82-83 (Haw. 1987) (applying pure comparative negligence to strict products liability actions); *see also* Ex. 37 (additional variations).

- In some jurisdictions, a successful defense of assumption of risk is a complete bar to recovery. *See Deere & Co. v. Brooks*, 299 S.E.2d 704, 707 (Ga. 1983); *Hogue v. A. B. Chance Co.*, 592 P.2d 973, 975 (Okla. 1978); *see also* Ex. 37 (additional variations).[30]

- A rebuttable presumption arises under Tennessee law that Zometa® and Aredia® are not unreasonably dangerous if NPC complied with federal and state regulations, *see* Tenn. Code Ann. § 29-28-104 (2007), whereas in New Mexico such compliance is merely admissible evidence for the defense. *Fabian v. E. W. Bliss Co.*, 582 F.2d 1257, 1261 (10th Cir. 1978) (citing *Lopez v. Heesen*, 365 P.2d 448 (N.M. 1961)); *see also* Ex. 37 (additional variations).

4. Applying the choice of law principles to each plaintiff's claim creates numerous individual inquiries predominating over any common questions.

A federal court sitting in diversity must apply the choice of law principles of the forum state.[31] *Erie*, 304 U.S. at 77-78. Under Tennessee's choice of law principles, for each plaintiff,

[30] Assumption of risk may play a key role in the resolution of plaintiffs' claims. For example, both putative class representatives received doses of either pamidronate or Zometa® *after* learning of the alleged increased risk of developing ONJ. Lee requested and received pamidronate in December 2006, months after telling one of her physicians that she was concerned about her alleged increased risk. *See* Lee_C-0448-0052-53; Lee Dep. at 153:9-17. Duncan received a second dose of Zometa® after discussing the alleged risk of developing ONJ with her oncologist. Duncan_S-0879-0041.

[31] Neither the existence of the MDL nor diversity jurisdiction under the Class Action Fairness Act ("CAFA"), Complaint at ¶ 37, changes the required choice of law analysis. *See In re Auto. Refinishing Paint Antitrust Litig.*, No. 1426, 2007 WL 1377700, at *3 (E.D. Pa. May 8, 2007) (in case filed under CAFA and transferred into MDL, federal court sits in diversity jurisdiction and applies the substantive law of appropriate state) (quotations omitted) (Ex. 38). Because this Court is the transferor court, Tennessee's choice of law rules apply. *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 241 F.R.D. 185, 193 (S.D.N.Y. 2007) (district court addressing class certification in MDL proceeding must apply choice of law of the transferor court); *In re Reciprocal of Am. Sales Practices Litig.*, No. 04-2313, 2006 WL 1699403, at *5 (W.D. Tenn. June 13, 2006) (MDL 1551) (same) (Ex. 39).

the Court must identify which jurisdictions' law(s) could apply, determine whether there is a conflict between those law(s) and Tennessee law, and, if so, decide which state has the most significant relationship to the claims. *Glennon v. Dean Witter Reynolds, Inc.*, 83 F.3d 132, 136 (6th Cir. 1996); *Hataway v. McKinley*, 830 S.W.2d 53, 59 (Tenn. 1992).

Because conflicts on medical monitoring, negligence, and strict liability laws exist, this Court must determine which jurisdiction has the most significant contacts with each putative class member's claim. The Court must examine several factors, all of which are plaintiff-specific, including: where each putative class member's alleged injury occurred; the place where the conduct causing the injury occurred; the domicile, residence, nationality, place of incorporation and place of business of the parties; and the place where the relationship, if any, between the parties is centered. *Glennon* 83 F.3d at 136; *Hataway*, 830 S.W.2d at 59.

Lee has moved between Florida and Georgia, receiving medical treatment in each. She currently lives in Georgia and records indicate she used pamidronate there. Florida recognizes medical monitoring; Georgia does not. Duncan received her relevant medical treatment in California. The only connection between Duncan or Lee and Tennessee is this MDL.

Plaintiffs assert that California law applies to Duncan's claim and Georgia law applies to Lee's claim, Docket #580 at 40, and that assessment is consistent with Tennessee's choice of law rules, under which the laws of the jurisdiction where exposure to Aredia® or Zometa® occurred are most likely to apply. *See Hataway*, 830 S.W.2d at 59. However, what law applies can only be determined after an individual analysis of each putative class member's medical history.[32]

[32] The choice of law analysis becomes more complex when a putative class member received Aredia® or Zometa® in multiple states. For example, a former putative class representative in this litigation allegedly received Aredia® in West Virginia, Arkansas, and Ohio. *See* Woollard_R-0109-0199, 0209-0210, Woollard_R-0139-3093, Woollard_R-0152-0933 (Ex. 40).

The choice of law analysis is more than a formality – as seen with Lee, a plaintiff who may have a medical monitoring claim under one possibly applicable jurisdiction's law could be barred under another. Both NPC and plaintiffs are entitled to have the correct law applied to each class member's claims.

B. The Number and Significance of the Other Individual Issues Raised by the Proposed Dental Monitoring Class Outweigh Any Common Issues and Defeat the Predominance Requirement of Rule 23(b)(3).

Regardless of whether the putative class members' claims are governed by the law of one, 13, or 34 jurisdictions, medical monitoring claims raise many individual issues preventing certification under Rule 23(b)(3). *In re St. Jude Med.,* 425 F.3d at 1122 (where each plaintiff requires different monitoring or treatment, individual issues predominate and certification is inappropriate, particularly where plaintiffs have differing levels of exposure to drugs); *In re Baycol*, 218 F.R.D. at 208 (same); *In re Rezulin*, 210 F.R.D. at 66-67 (same); *Blain*, 240 F.R.D. at 191 ("number and complexity of the questions that must be resolved to determine liability in each individual's case predominate over common questions"); *see Barnes*, 161 F.3d at 146 (even where one jurisdiction's law applies to class, need for medical monitoring program requires an examination of each plaintiff's history and condition, raising numerous individual issues barring certification under 23(b)(3); denying Pennsylvania medical monitoring class); *Perez*, 218 F.R.D. at 273 (denying certification of a Florida medical monitoring class).

1. Individual issues are inseparable from the causation inquiry.

The causation inquiry for medical monitoring purposes is not who used Aredia® or Zometa® (which is an individual question – *see infra*), but who is at an alleged increased risk of developing ONJ solely because of Aredia® or Zometa® use. *See Thompson*, 189 F.R.D. at 555-56 (rejecting certification where proposed medical monitoring plan required analysis of each class member's medical history to determine whether need for medical monitoring was solely

due to smoking and not other risk factors); *Blain*, 240 F.R.D. at 185 (causation inquiry is not limited to who used drug, but also whose alleged injuries were caused only by drug); *Sanders*, 2006 WL 1541033, at *9 (same); *Bethards v. Bard Access Sys., Inc.*, No. 94C1522, 1995 WL 75356, at *7 (N.D. Ill. Feb. 22, 1995) (causation is an individual inquiry because any question of whether product has "capacity to cause harm is really a particular determination of whether the [product] did cause harm, and if so, to whom") (Ex. 41).

There are several risk factors for ONJ, many of which appear frequently in this plaintiff population. For example, Lee and Duncan (and likely many putative class members) received different combinations of chemotherapy and corticosteroid therapy.[33] Reports linking these treatments to ONJ pre-date the availability of Aredia® and Zometa®. *See, e.g.,* Schwartz, H. *Osteonecrosis of the Jaws: A Complication of Cancer Chemotherapy*. Head & Neck Surgery (1982) Jan./Feb.:251-253 (Ex. 42); Lipton Dep. at 35:5-36:14 (aware of reports of ONJ in cancer patients receiving chemotherapy, radiation, and corticosteroid treatments in 1970s or 1980s); Coleman Dep. at 139:16-22 ("dental complications during chemotherapy are, by no means, uncommon"); Russell Rep. at 32.

Lee's medical history discloses other reported risk factors for ONJ including: conditions such as diabetes and a history of strokes that demonstrate impaired blood circulation throughout the body (including to her bones), smoking, prior jaw and facial trauma, and jaw related nerve damage. *See* Lee Dep. at 96:14-15 (diabetes), 13:17-21 (two strokes); *id.* at 107:9-22 (smoked half a pack a day for twenty years); *id*. at 85:13-87:18 (in approximately 1988, suffered face laceration requiring 160 stitches); Lee_C-1211-0045-46 (diagnosis of trigeminal neuralgia,

[33] Lee received corticosteroids for non-cancer indications beginning in 1993, with particularly high doses for several months in 2000 and 2001. *See* Lee_C-0975-0078; Lee_C-1132-0104; Lee_C-0448-0110-12. Since 2002, Lee has taken a chemotherapy drug to treat dermatomyositis. Lee Dep. 131:20-132:2; Lee_C-1079-0029. Duncan, who has

which occurs when nerves controlling jaw are damaged); Stanton Rep. at 20; Russell Rep. at 14. Lee had no dental treatment from 1984 to 2002 and limited treatment since that time, so that infections, abscesses, and other problems went untreated. Stanton Rep. at 20; Lee Dep. at 202:17-205:3 (left deposition because of pain from root canal); *see also* Stanton Rep. at 20 (rheumatoid arthritis places Lee at risk of dry mouth, which increases her risk of cavities and periodontal disease).

Duncan has a different set of risk factors for ONJ, including multiple forms of cancer. Stanton Rep. at 17-18. She has several bone-related problems, including osteoporosis (thin or weakened bones) and a history of poor bone healing. *See* Duncan_S-0976-0038 (osteoporosis diagnosed almost eight years before first alleged use of Zometa®); Deposition of Sybila Duncan at 85:18-23, 136:16-24 (broken bones failed to heal after automobile accident that occurred three years before first alleged use of Zometa®) ("Duncan Dep. ") (Ex. 43). Despite instructions from her physicians, Duncan exacerbates her weakened bone condition by taking more than the recommended amount of her thyroid medication, which she knows can accelerate osteoporosis. Duncan_S-0976-0038, 0976-0046, 0976-0056. Prior to her use of Zometa®, doctors determined that Duncan was highly prone to developing cavities, and she underwent multiple prior dental restorations, including crowns and root canal therapies. Stanton Rep. at 17. Additionally, she received radioactive iodine therapy that may have adversely affected her salivary gland function, thus increasing her risk of developing cavities and periodontal disease. *Id.*

Determining whether or why each putative class member is at an increased risk of developing ONJ caused by Aredia® or Zometa® use requires an analysis of each individual's medical and dental history and consideration of each person's unique potential risk factors.

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metastatic breast cancer, received corticosteroids and chemotherapy. *See* Stanton Rep. at 17-18; Russell Rep. at 13-14; Coleman Rep. at 4-5.

Plaintiffs focus almost entirely on the merits of the causation issue, presupposing that any class member's purported increased risk of developing ONJ results only from Aredia® or Zometa® use. Docket #580 at 3-10, 16-29. Their analysis misses the point.[34] Under Rule 23, the question is not whether Aredia® and Zometa® are possible risk factors for ONJ, but instead whether, in an aggregate proceeding, Aredia® or Zometa® can be isolated as the sole factor placing all members of the class at increased risk of developing ONJ for which a uniform monitoring plan is appropriate. This question could never be answered in the aggregate because no two plaintiffs are the same – not even those who appear to have similar underlying destructive bone diseases. Plaintiffs cannot overcome the fact that any analysis of causation must consider each plaintiff's unique circumstances. Coleman Dep. at 156:8-157:6; *see also Amchem*, 521 U.S. at 623-24 (exposure to same substance is not sufficient to satisfy predominance where individual issues exist); *Sanders*, 2006 WL 1541033, at *6 (same).

Although plaintiffs rely on the causation opinions of statistician Wayne Taylor, Ph.D., *see* Docket #580 at 16, Taylor's testimony undermines their class certification arguments by showing that there is no one-size-fits-all approach to determining whether Aredia® and Zometa® cause ONJ on a class-wide basis. For example, Lee received pamidronate for Paget's disease and did not have cancer. However, Taylor admitted that his opinions are "limited to whether Aredia or Zometa cause ONJ in cancer patients." Deposition of Wayne Taylor at 165:6-15 ("Taylor Dep.") (Ex. 44). Taylor's causation opinions do not apply to Lee or to any member of the putative class who does not have cancer.

[34] Plaintiffs' mischaracterizations aside, NPC's experts have consistently opined that there is no reliable scientific evidence establishing that Aredia® or Zometa® cause ONJ. *See* Stanton Rep. at 9; Stadler Rep. at 4; Lipton Rep. at 7; Coleman Rep. at 18; Russell Rep. at 18, 33; Expert Report of Mitchell Levine at 11 (Docket #619); *see also* Van den Wyngaert Art. at 321 (causal relationship not established). However, at the class certification stage, this Court need not resolve the causation dispute.

Moreover, even if the class included only Aredia® or Zometa® users *with cancer* who have not developed ONJ (which is narrower than plaintiffs' proposed class), Taylor's testimony shows that the issue of causation is not susceptible to resolution on a class-wide basis. For instance, Taylor concedes that, "in multiple myeloma patients, [he] can't reach a scientifically reliab[le] conclusion that bisphosphonates cause ONJ." Taylor Dep. at 418:20-419:2.

In sum, individual issues, including disease type, are inseparable from the causation inquiry and would need to be resolved.[35]

2. Determining liability also requires individual adjudication.

Plaintiffs' claims also require individual determinations that can only be made by examining facts unique to each plaintiff's use of Aredia® and/or Zometa®, what each plaintiff or his physician understood about the risks of the product, and/or whether plaintiff's other medical conditions or risk factors could cause an increased risk of developing ONJ. Plaintiffs who knew about the alleged increased risk of developing ONJ and used either product will be unable to recover in most jurisdictions. *See supra* at 33. One source of information about a drug is its labeling and with FDA approval, labeling changes related to ONJ occurred in 2003 and 2004 for Aredia® and Zometa®. *See* Arrowsmith-Lowe Report at 3-4. As a result, prescribers and users of the drug(s) could have received and/or conveyed different information at different times regarding the alleged risk of ONJ. *See* Deposition of Janet Arrowsmith-Lowe at 116:7-117:4 (changes in indications and labeling mean users of these drugs are "quite heterogeneous") (Ex.

[35] A finding of "causation" unconnected with a specific plaintiff would not materially advance the litigation as required by *Sprague,* 133 F.3d at 397. *See In re Prempro*, 230 F.R.D. at 570 (showing of "causation in the air" is not sufficient to satisfy Rule 23; class action is not superior when extensive individual adjudications would still be required); *Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667, 677 (N.D. Ohio 1995) (determining whether drug ever causes certain effects "accomplishes nothing for any individual plaintiff"); *Jones v. Allercare*, 203 F.R.D. 290, 302 (N.D. Ohio 2001) (same); *Harding*, 165 F.R.D. at 630 (same).

45). For example, when Duncan received Zometa® in December 2006, the label provided different information than before the first ONJ-related labeling change in 2003.

In addition to labeling, physicians also provide patients with individualized information about prescription drugs. *See, e.g.,* Coleman Dep. at 199:17-200:8 (information given to patients varies based on examination and medical history; "relevance that I might put on the dental complications or dental events while they're having treatment, . . . whether it was chemotherapy or this bisphosphonate, would depend on that consultation"); Lipton Rep. at 11; Stadler Rep. at 3; *compare* Waisman Dep. at 81:20-82:4 (aware of first case of ONJ in bisphosphonate user in 2004), *with* Stoever Dep. at 18:9-12 (became aware of allegations regarding bisphosphonates and ONJ in 2006). Each plaintiff also may have gathered different information on his own. *See* Lee Dep. at 150:3-25, 153:6-14 (learned of alleged ONJ risk from "e-mail" prior to last dose); Duncan Dep. at 142:6-144:2 (learned of alleged increased risk through internet research conducted between first and second infusions).

Where labeling and available information regarding the drug differs among class members, failure to warn issues are not common. *Sprague*, 133 F.3d at 398 (commonality not met where class members received different information and resolution of claims requires individual proof); *In re Am. Med. Sys.*, 75 F.3d at 1085 (predominance is not satisfied where different products are involved, each plaintiff has a "unique complaint," and "each receive[d] different information and assurances from his treating physician"); *Harris*, 218 F.R.D. at 596 (inquiry into what each physician knew and what he told each plaintiff is "highly individualized"); *Dhamer*, 183 F.R.D. at 531-32 (because of changes in available information over time and involvement of many physicians, "it is likely that no two patients receive[d] exactly the same information," therefore individual issues predominated); *Lewallen*, 2002 WL

31300899, at *4 (individual questions predominated, including what each physician knew and when, and what information each doctor provided to each patient); *Sanders*, 2006 WL 1541033, at *6 (same); *see also* Stanton Rep. at 15; Lipton Rep. at 11; Arrowsmith-Lowe Rep. at 3.

V. PLAINTIFFS' PROPOSED DENTAL MONITORING CLASS DOES NOT SATISFY RULE 23(b)(3)'S SUPERIORITY AND MANAGEABILITY REQUIREMENTS.

Certification under Rule 23(b)(3) is proper only if plaintiffs demonstrate that "a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). The four non-exclusive criteria used to determine if the superiority requirement is met are: (1) the interest of class members in individually pursuing their claims, (2) the extent and nature of individual actions already commenced, (3) the desirability of concentrating the litigation in a particular forum, and (4) the difficulties likely to be encountered in the management of a class action. Fed. R. Civ. P. 23(b)(3).

"Superiority" does not mean the creation of a mechanism that makes it more likely plaintiffs will prevail. Rather, it relates to the efficiency of resolving the claims aggregately. *Johnston v. HBO Film Mgmt., Inc.*, 265 F.3d 178, 185 (3d Cir. 2001) ("a class action [must be] the best method of fairly and efficiently resolving the controversy") (citations omitted). Where individual issues pervade plaintiffs' claims, aggregate resolution is not efficient and superiority fails. *Castano*, 84 F.3d at 749-50; *Perez*, 218 F.R.D. at 273 (denying class certification of medical monitoring claims, in part, because determination of whether medical monitoring elements were met by each plaintiff would "make the process difficult and inefficient").

Plaintiffs' seven-sentence "superiority argument" asserts that individual class members lack the incentive to bring separate medical monitoring claims. However, plaintiffs ignore that some or all of the putative class members could benefit from proceeding independently of the doubtful viability and complexities of the class as defined here.

Whether claims can be manageably tried aggregately is often the deciding factor in the superiority analysis, yet plaintiffs provide no analysis of it. *See Cimino v. Raymark Indus., Inc.*, 151 F.3d 297, 312 (5th Cir. 1998) (plaintiffs must provide trial plan permitting adjudication without altering parties' substantive rights). Plaintiffs focus solely on whether notice can be supplied to class members, and even then their assumptions and analyses are wrong.

A. Plaintiffs Have Not Met Their Burden of Providing a Trial Plan That Would Allow Numerous Individual Issues To Be Manageably Resolved in an Aggregate Proceeding.

In any of the possible class formulations, variations in state laws cannot be accommodated in one proceeding. *See Castano*, 84 F.3d at 743 n.15 (variations in laws on product liability and affirmative defenses prevented manageable aggregate trials); *In re Am. Med. Sys.*, 75 F.3d at 1085 (trial involving differing negligence laws in multiple jurisdictions would be unmanageable and defeats certification); *Clay v. Am. Tobacco Co.,* 188 F.R.D. 483, 501-02 (S.D. Ill. 1999) (class-wide resolution of strict liability claims is unmanageable because elements vary from jurisdiction to jurisdiction); *Blain*, 240 F.R.D. at 194-95 (choice of law problems made the proposed nationwide class unmanageable); *Sanders*, 2006 WL 1541033, at *5-6 (applying laws of multiple jurisdictions would be unmanageable in part because state law causes of action based on negligence, strict liability, and medical monitoring differ).[36] Furthermore, regardless of the number of jurisdictions included in the putative class, there is no manageable way to try the dental monitoring claims in a single proceeding given the prevalence of other individual issues. *See, e.g., Castano*, 84 F.3d at 745 n. 19 ("[t]he greater the number of individual issues, the less likely superiority can be established"); *see supra*.

[36] Even in the proposed California resident-only class, there likely are individuals who used either or both drugs in other states. For those individuals, another jurisdiction's law may apply to their claims. Therefore, limiting the class to one state does not allow plaintiffs to circumvent the choice of law analysis required for every class member.

Even if some issues on the periphery of plaintiffs' claims were capable of common resolution, individual trials still would be required on the material elements of causation, liability (including affirmative defenses), and other questions. Where numerous individual trials will be required, class resolution of any issue is not superior. *In re Am. Med. Sys.*, 75 F.3d at 1085 ("unique problems of each plaintiff would present a nearly insurmountable [manageability] burden on the district court"); *see also Castano*, 84 F.3d at 740 (rejecting district court's finding that a class action was superior to the "specter of thousands, if not millions, of similar trials of liability proceeding in thousands of courtrooms around the nation;" there was no aggregate way to resolve uniquely individual issues such as causation); *Perez*, 218 F.R.D. at 272 (class would be required to show proximate causation to prevail; addressing proximate cause on aggregate level would be unmanageable where multiple medical problems of each putative class member must be analyzed to determine cause of alleged increased risk); *Arch*, 175 F.R.D. at 492 (superiority requirement is not satisfied where "there are simply too many individual issues and class members to try this case efficiently," creating "staggering" manageability problems).

B. Plaintiffs' Proposed Notice Plan Demonstrates Why the Putative Class Is Unmanageable.

To satisfy superiority, plaintiffs also must show that Rule 23's requirements regarding notice can be met and that adequate notice can be provided. *Castano*, 84 F.3d at 747 (manageability problems, including providing notice, defeated superiority under Rule 23(b)(3)); *Burns v. First Am. Bank,* No. 04-C-7682, 2006 WL 3754820, at *11 (N.D. Ill. Dec. 19, 2006) ("difficulties in identifying and notifying class members" are proper considerations for determining manageability) (Ex. 46). Plaintiffs' proposed notice plan fails in four key areas:

1. The "notice plan" provides no opportunity to opt out of the class.

The ability of a class member to "opt out" of a class certified under Rule 23(b)(3) is a central component of the rule and necessary to protect absent members' due process rights because, unless a potential member opts out, he will be bound by the class judgment. *See Matsushita Elec. Indus. Co. v. Epstein,* 516 U.S. 367, 379 (1996); *Phillips Petroleum Co. v. Shutts,* 472 U.S. 797, 812 (1985); Fed. R. Civ. P. 23(c)(2)(B). Nevertheless, according to plaintiffs' expert, the proposed notice plan currently does not include a method by which plaintiffs may opt out of proceeding as a member of the putative class. *See* Mulholland Dep. at 127:15-128:6.

2. The "notice plan" does not provide actual notice to putative class members known to plaintiffs' counsel.

Rule 23(b)(3) class members must receive the "best notice practicable under the circumstances." Fed. R. Civ. P. 23(c)(2)(B). Individual notice must be provided to "all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2); *see Eisen,* 417 U.S. at 175 (1974); *Mullane v. Central Hanover Bank & Trust Co.,* 339 U.S. 306, 318 (1950). Although plaintiffs claim that direct mailings to users of Aredia® or Zometa® are not possible because class members cannot be identified, Docket #580 at 44, plaintiffs' counsel have admitted they know the identity of some putative class members. *See* Response By Plaintiffs' Steering Committee to Defendant Novartis' Motion to Dismiss Class Definition, Docket #350 at 9 ("although all of us had received inquires from persons who had a drug history but no side effect, we had turned them away"). The plan makes no provision for providing direct notice to those individuals.

3. Plaintiffs' plan does not provide adequate notice to absent class members.

Plaintiffs wrongly seek to evade their burden of providing notice to putative class members by suggesting non-parties should handle it. For example, plaintiffs' proposed notice program would require medical or dental professional organizations and individual physicians or dentists to "tell[] their patients about the program." Docket #580 at 44. Physicians also would be responsible for "posting" the notice in their offices, and directly contacting possible class members via mail, facsimile, or telephone. Mulholland Report at 8 ("Mulholland Rep.") (Docket #587). Plaintiffs also propose that notice be published on one occasion in "various industry publications," in the hope that healthcare providers will pass along the information. *See* Docket #580 at 44. Mulholland calls for publication of the notice on the professional organizations' or journals web sites. Mulholland Rep. at 11.

It is wildly speculative to suggest that any potential class member reads or visits the web sites of the *Journal of Clinical Oncology*, *Journal of Oral and Maxillofacial Surgery*, *Journal of Periodontology*, or the *Journal of the American Dental Association*. Even if they did, the obligation to provide notice to absent class members is class counsel's; neither the responsibility nor cost can be shifted to non-parties. *See, e.g., Oscar Gruss & Son v. Geon Indus., Inc.,* 89 F.R.D. 32, 39 (S.D.N.Y. 1980) (refusing to order non-parties to distribute or bear cost of plaintiffs' notice program); *cf. Oppenheimer Fund, Inc., v. Sanders,* 437 U.S. 340, 359 (1978) ("the representative plaintiff should bear all costs relating to the sending of notice because it is he who seeks to maintain the suit as a class action"); *Peil v. Nat'l Semiconductor Corp.*, No. 77-4244, 1986 WL11699, *6 (E.D. Pa. Oct. 16, 1986) (plaintiffs must reimburse subpoenaed non-party brokerage firms for the costs associated with identifying class members) (Ex. 47). Where there is no assurance that plaintiffs' proposed notice would reach putative class members, the plan is not manageable. *See Barniger v. Nat'l Mar. Union,* 372 F. Supp. 908, 912-13 (S.D.N.Y.

1974) (where class members could not be identified and notice would not be guaranteed to reach members, notice program was not feasible).

Even accepting the doubtful proposition that some physicians would agree to participate – a proposition which plaintiffs do not and cannot suggest they know to be true – discussing a patient's legal rights is not within the scope of a physician's medical training, qualifications, or experience, and would divert attention from the treatment of seriously ill cancer patients (which physicians are uniquely qualified to handle) to discussions of legal rights (which is more correctly the responsibility of putative class counsel). Mulholland Dep. at 211:22-212:3; *see also* Arrowsmith-Lowe Rep. at 7. Treating physicians cannot and should not answer a putative class member's legal questions. Mulholland Dep. at 212:8-21; Arrowsmith-Lowe Rep. at 7.[37] Moreover, each putative class member would likely receive mixed or conflicting messages about his class eligibility depending upon how the medical practitioner interprets the notice. *See* Arrowsmith-Lowe Rep. at 5; *see also* Mulholland Dep. at 231:16-232:22 (indicating that plaintiffs currently have no plan to address problem of differing information given to putative class members).

Plaintiffs also propose publishing the notice in *USA Today*, *The New York Times*, and note that "other major newspapers that can be utilized include *The Wall Street Journal*, *Los Angeles Times* and *Chicago Tribune*." Mulholland Rep. at 9. But plaintiffs do not explain how publishing notice in two papers (or possibly a few others) satisfies their burden to provide a manageable notice plan reasonably tailored to reach absent class members.

[37] Physicians and dentists generally do not discuss litigation matters in their office and would find the requirement of doing so an intrusion into the physician-patient relationship. *See* Stanton Rep. at 15; *see also* Arrowsmith-Lowe Rep. at 5-7. The notice plan also risks interfering with FDA's sole and comprehensive control over the means by which prescription drug product information may be disseminated. *Id.* at 5-7.

In addition, plaintiffs' "expert" on notice issues actually knows little to nothing about the viability of the proposed notice at all. Mulholland has disavowed any expertise in developing a manageable notice plan and has admitted that someone else (who was not identified by plaintiffs as an expert witness) wrote that portion of his report. Mulholland Dep. at 81:1-12. Mulholland testified that he has no opinion on key aspects of the notice plan, such as who should receive notice or what the notice would say. Mulholland Dep. at 143:20-144:8 (no opinion on what notice will say regarding ONJ or either drug); *id.* at 151:4-152:2, 224:1-225:1 (does not know what physicians should discuss with potential plaintiffs regarding notice, medical monitoring claims, who is or is not in class, opt out rights, contact information for class counsel, or coupon program which he is charged with administering). By producing a witness who was not responsible for preparing the notice plan and who could not answer meaningful questions about it, plaintiffs failed to meet their burden of showing notice is manageable or even feasible. *See also* NPC's Motion to Strike Report and Testimony of Paul Mulholland (Docket ##624, 625).

VI. PLAINTIFFS' DENTAL MONITORING PLAN FAILS TO MEET THE REQUIREMENTS OF RULE 23(a) AND 23(b)(3).

The medical monitoring plan proposed by plaintiffs suffers from many of the same flaws as their request for certification of medical monitoring claims generally. Plaintiffs try to standardize the number of dental examinations available to putative class members, requiring that participants receive two examinations per year. As such, the proposal wrongly amounts to a request that NPC pay for routine dental care; indeed for some individuals the proposed care is less than what is medically recommended wholly apart from Aredia® or Zometa® use. *See, e.g., Potter*, 863 P.2d at 825 (no recovery for preventative care to which public should already

submit); *Perez*, 218 F.R.D. at 273-4, 275.[38] For example, professional organizations recommend that individuals with cancer or who are receiving chemotherapy or corticosteroids undergo exams as needed to maintain good oral hygiene and prevent infection.[39]

How many and how often exams are needed in reality can only be determined on an individual basis, preventing certification.[40] *See Arch*, 175 F.R.D. at 490 ("Medical necessity thus widely fluctuates among class members. It appears that these issues cannot be resolved on a class-wide basis."); *Lewallen*, 2002 WL 31300899, at *4 (issues such as what monitoring (if any) is required for each patient are additional individual questions of fact that prevent certification). The need for individual adjudication of this issue prevents certification under the commonality, typicality, adequacy, predominance, and superiority requirements of Rule 23.

Plaintiffs' medical monitoring proposal for uniform semi-annual screening radiographs is also not appropriate for each member of the putative class. In fact, putative representative Duncan has refused to have recommended radiographic screenings on multiple occasions, *see* Duncan_S-1114-0004; Duncan Dep. at 183:18-184:7, though she now proposes them class-wide.

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[38] Everyone should have two examinations per year, regardless of whether he uses Aredia® or Zometa®. Marx Rep. at 41; *see also* Lipton Dep. at 180:25-181:1-5 (every person, regardless of medical conditions, needs dental care); Stanton Rep. at 21 ("[t]he clinical portion of [plaintiffs'] monitoring program is no different than the semiannual dental evaluations that should be obtained as part of routine dental care. More frequent dental evaluations are already recommended for immunosuppressed patients, such as those undergoing systemic chemotherapy"); Plaintiffs' Compendium of Medical and Scientific Articles, Exhibit 29 (Migliorati C., et al., *Managing the Care of Patients with Bisphosphonate-Associated Osteonecrosis: An American Academy of Oral Medicine Position Paper*, at 1664 ("It is recommended that dentists follow *existing guidelines* for a dental consultation [with bisphosphonate treated patients] for the prevention of oral complications of cancer therapy (chemotherapy, radiation therapy, prehematopoietic stem cell transplantation)") (emphasis added).

[39] *See, e.g.,* Oral Care for Cancer Patients, *J. A. Dental Assoc.* (2002) 133:1014 (patients who undergo cancer treatment should "schedule a thorough dental checkup at least two weeks before treatment begins" and "schedule regular dental checkups" thereafter) (Ex. 48); Nat'l Inst. of Health, *Chemotherapy and Your Mouth* at 5, 11 (Sept. 2005) ("dentists will do a complete exam" prior to cancer treatment, including x-rays and "tak[ing] care of mouth problems;" thereafter, "[t]alk regularly with your cancer doctor or dentist about **any** mouth problems you have") (emphasis in original) (Ex. 49); Lipton Dep. at 178:23-180:5 (informs all chemotherapy, steroid treatment or stem cell treatment patients to obtain a good dental examination and treatment prior to therapy).

[40] *See* Stanton Dep. at 255:22-256:6 (each plaintiff needs dental care "tailored to the individual, their caries rate, their rate of periodontal disease, their individual disease process. It would vary from person-to-person"); Marx Dep.

Plaintiffs' expert recognizes that an individual patient's dentist is in the best position to determine when x-rays are needed. Marx Dep. at 146:14-147:11; *see also* Stanton Dep. at 70:17-72:7 (such decisions should be made by an individual and his physician). And, in any event, plaintiffs' proposal is unnecessary – radiographs as needed are recommended for this plaintiff population even if they had not used Aredia® or Zometa® due to the dental health risks posed by the bone disease itself and treatments, such as chemotherapy. Stanton Rep. at 11, 21.

Marx also concedes that there is no scientifically reliable evidence that the plan would predict ONJ in putative class members prior to the clinical presentation of exposed bone; his proposed "subclinical toxicity" testing yields, at best, subjective results that must be interpreted on an individual basis. *See* Marx Dep. at 404:9-405:1 (diagnosis of "subclinical bisphosphonate toxicity" is made in own professional judgment on individual basis); *id.* at 408:6-409:19 (error rate of proposed plan is untested); *id.* at 409:20-25 (other than own textbook, no published literature supporting proposed plan) (Ex. 22); *see also* Stanton Rep. at 11-14, 21.[41] Assuming admissibility of a plan for which no scientifically reliable support exists, whether any patient requires radiographs is at best an inherently individual determination.[42]

Finally, a medical monitoring class action is not "superior to other available methods" of resolution when, as here, neither FDA nor relevant professional organizations have called for the medical monitoring plan suggested by plaintiffs' expert. *See In re Propulsid*, 208 F.R.D. at 147 (request for class not timely where, apart from plaintiffs' expert, neither FDA nor relevant

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at 133:13-134:1 (admitting that how often patients need dental check-ups and radiographs is a part of an individualized plan).

[41] Plaintiffs' expert would not treat "pre-ONJ" patients differently from those not showing the supposed signs of its development. *See* Marx Dep. at 440:14-442:10.

[42] Plaintiffs' plan is also medically irresponsible because it may discourage health care professionals from performing needed dental surgeries or other procedures on plaintiffs using Aredia or Zometa. *See* Stanton Dep. at 258:6-16 (if patient has abscess that must be drained to prevent life threatening infection, need to do so regardless of bisphosphonate use).

organizations suggested the need for medical monitoring); *In re Baycol*, 218 F.R.D. at 212 (denying certification of (b)(2) medical monitoring class because of "lack of medical or scientific evidence, with the exception of Plaintiffs' expert, which suggests or recommends" that putative class members should have certain tests); *In re Rezulin*, 210 F.R.D. at 73 (same); *Sanders*, 2006 WL 1541033, at *10 (same); *Wyeth Inc. v. Gottlieb*, 930 So. 2d 635, 642 (Fla. Ct. App. 2006) (reversing trial court's grant of class certification of Prempro users in part because "neither the FDA, nor any other medical organization, has recommended or developed a medical monitoring program for current or former Prempro users").

CONCLUSION

For all of the above reasons, class certification should be denied.

Respectfully submitted,

September 17, 2007

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 17th day of September 2007 served a true and correct copy of the foregoing Novartis Pharmaceuticals Corporation's Memorandum in Opposition To Plaintiffs' Motion for Certification of a Dental Monitoring Class, by operation of the Court's Electronic Case Filing System, on Plaintiffs' Liaison Counsel:

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